CANE
MEDICAL TECHNOLOGY

CRONO PAR 50

Ambulatory infusion pump

USER GUIDE

CANÈ S.p.A. Medical Technology
Via Cuorgnè 42/a 10098 Rivoli (TO) Italy
Tel.+39 011 9574872 - Fax +39 011 9598880
www.canespa.it - mailbox@canespa.it

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SYMBOLS AND CONVENTIONS

To assist you in using the manual, the following symbols and conventions have been used:

Triangle containing an exclamation mark
This "**WARNING**" icon indicates something that must always be taken into consideration for the safe use of the pump.

Notepad
This icon indicates a "**NOTE**" containing additional information or useful tips about the use of the pump.

Flashing symbol
The graphic symbol shown in the manual above the pictures of the pump display, indicates that the number or the character below it is flashing.

This manual is divided into 6 parts:

Part 1 (red): sections 1 to 8, general information, technical specifications and warnings.

Part 2 (blue): sections 9 to 11, describing the working of the pump when **FrEE** mode has been selected.

Part 3 (green): sections 12 to 14, describing the working of the pump when **Auto** mode has been selected.

Part 4 (orange): section 15, which describes the *reservoir*, the preparation and connection of the *reservoir* to the pump, the infusion sites and the preparation for an infusion.

Part 5 (purple): sections 16 and 17, giving general warnings and a description of the supplied standard equipment, as well as discussing maintenance, disposal and support. It also details the guarantee and the declaration of conformity.

Part 6 (grey): appendices page 95 to page 114.

INTRODUCTION

Thank you for choosing the ***CRONO*** **PAR 50** ambulatory infusion pump.

If any of the information is not clear, or if you have any doubts or questions, please contact the Customer Support Service of CANÈ S.p.A.

Incorrect use of the pump, or failure to follow the instructions and warnings provided in this manual could cause serious injury.

The instructions provided relate exclusively to the ambulatory infusion pump, model ***CRONO*** **PAR 50**. They are intended for use by the medical and paramedical personnel who need to set up the pump initially and subsequently by patients who are capable of managing their treatment autonomously, or persons who are caring for patients.

The pump offers two different programming modes:
- one called **FrEE**, that allows the patient to freely select, during the day, one of the 3 available flow rates pre-programmed by the doctor;
- one called **Auto,** that administers different flows pre-programmed by the doctor, automatically switching among them over the daily 24 hours.

The pump has a settings lock system (see page 25) which stops the settings from being modified by accident: the purpose of the settings lock function is to prevent accidental changes to the settings.

The ***CRONO*** **PAR 50** pump allows the medical/paramedical and clinical engineering personnel, as well as the distributor, to set, if needed, the occlusion pressure level (**PL**).

Information on the selection of the pressure level (**PL**) is available in **APPENDIX 10** "**ACCESSING RESERVED SECTION**", together with instructions for resetting the infusion counter and programming the time and date; it is possible to remove this information from the manual (see page 111 and 112), as this information should not be disclosed to the patient.

The instructions provided in this manual are essential for the safe and correct use of the pump. You are advised to read the whole manual before starting to use the device and to refer the manual for future reference.

The pump does not need to be installed, tested and/or activated.

CANÈ S.p.A. reserves the right to modify the hardware and software specifications described in this manual at any time and without notice.

NOTES

• In order to make this manual as complete and accurate as possible, please report any errors or omissions to the following e-mail address: service@canespa.it.

• CANÈ S.p.A. reserves the right to modify and/or update this manual at any time and without notice.

WARNING: PRECAUTIONS FOR USE

This pump should not be used autonomously by patients who are not able to follow and understand the instructions supplied in this manual or able to perform the basic operations and the regular maintenance of the pump.

INFORMATION

For further information on the ***CRONO*** **PAR 50** pump, contact:

Servizio Assistenza Clienti (Customer Support Service)
CANÈ S.p.A. Medical Technology
Via Cuorgnè, 42/a
10098 Rivoli (Turin) - Italy
Tel. +39.011.9574872
Fax +39.011.9598880
Internet: www.canespa.it e-mail: service@canespa.it

Service available Monday to Friday from 8.30 to 17.00.

INTENDED USE

The ***CRONO*** **PAR 50** ambulatory infusion pump is designed for the subcutaneous infusion of apomorphine in the treatment of Parkinson's disease.

CANÈ S.p.A. disclaims all responsibility for the administration of drugs by other methods and for different therapies.

NOTE

The manufacturer holds itself responsible for the safety of patients and the correct functioning of the device provided that it is used in accordance with these instructions, and that any required repairs and/or modifications are carried out exclusively by the said manufacturer.

WARNINGS

The use of incorrect settings and/or incomplete understanding of the operational functions and of the alarms could cause serious harm to the patient.

The clock (hours and minutes) must be correctly set when the pump is in **Auto** mode, as the administration of the different flows is directly correlated to the daily 24 hours.
You are recommended to check the time displayed before every infusion.
It is further recommended to reset the clock at the beginning and end of Daylight Saving Time (Summer Time) and when changing time zone.

Before using the pump, evaluate whether its use is appropriate for the need and for the patient, paying close attention to the following aspects:
- the technical specifications of the pump;
- the infusion sets which will be used;
- whether you will be using multiple tube sets and *clamps* in the infusion line;
- The cognitive and psycho-physical condition of the patient.

With respect to the clinical procedural aspects, which are the responsibility of medical or paramedical personnel, the above list is supplied for example purposes only and is not exhaustive.

The device must be used:
- under medical supervision,
- with appropriate procedures and adequate measures when dealing with patients who could suffer serious consequences (injury or death) in the event of accidents and/or breakdowns which cause an interruption of the administration of the drug.

Do not *prime* the infusion line when it is connected to the patient, because this could cause an overdose of the drug.

Before beginning an infusion, inspect the infusion line to ensure there are no folds, *clamps* or other occlusions in the line, and expel any air bubbles.

The level of precision and the amount of time needed to detect an occlusion could differ from the values indicated in this User Guide for the elements composing the infusion line.

If you have any suspicion that the pump has been in any way damaged, for example by liquid penetration or having been dropped, contact the Customer Support Service to check that the pump is functioning correctly. Do not use a damaged pump.

If you have any doubts about the functioning of the pump and/or an error or anomaly occurs, stop using the device and contact the Customer Support Service.

CANÈ S.p.A. does not supply a replacement service for the pump during the period needed for any repairs; such a service should be supplied by the relevant medical structure or the local distributor.

Any liquid on the pump casing must be removed immediately with paper towels.

It is important to establish a procedure and/or alternative to pumped infusion, in case the pump malfunctions. Possible solutions could either be to have a secondary pump or to have an alternative system.

It is recommended that the individuals who assist and/or live with the pump user know how the pump works and the information in this User Guide.

It is important to stop using the device after the indicated service life has expired and follow the instructions for its correct disposal.

PUMP DESCRIPTION

***CRONO* PAR 50** is an ambulatory infusion pump which uses single-use *reservoirs* for the controlled subcutaneous administration of drugs containing apomorphine as the active ingredient, in the treatment of Parkinson's disease.

***CRONO* PAR 50** uses specific 50 ml syringes called *reservoirs*.

Its smaller size and reduced weight make ***CRONO* PAR 50** ideal for home use, thus giving the patient the freedom to engage in everyday activities during the treatment.

The technical characteristics of the pump are:
- the possibility of selecting two different modes of operation of the device, one of which has base-level functions - **FrEE** - while the other has more advanced functions for patients with greater therapeutic demands - **Auto**;
- a clock which allows administering different flow rates over a daily 24-hour period;
- twin microcontrollers making the device safer and more reliable;

The pusher mechanism acts directly on the piston of the *reservoir*, allowing the pump to administer the drug accurately.
For a better absorption of the drug, the pump administers 20 µl shots at intervals which depend on the flow rate chosen. If the programmed flow rate is increased, the time interval between the shots decreases proportionally.

***CRONO* PAR 50** has a liquid crystal display (LCD) which shows practical information to the doctor and patient about the settings, operations and diagnostics of the pump.

TECHNICAL CHARACTERISTICS

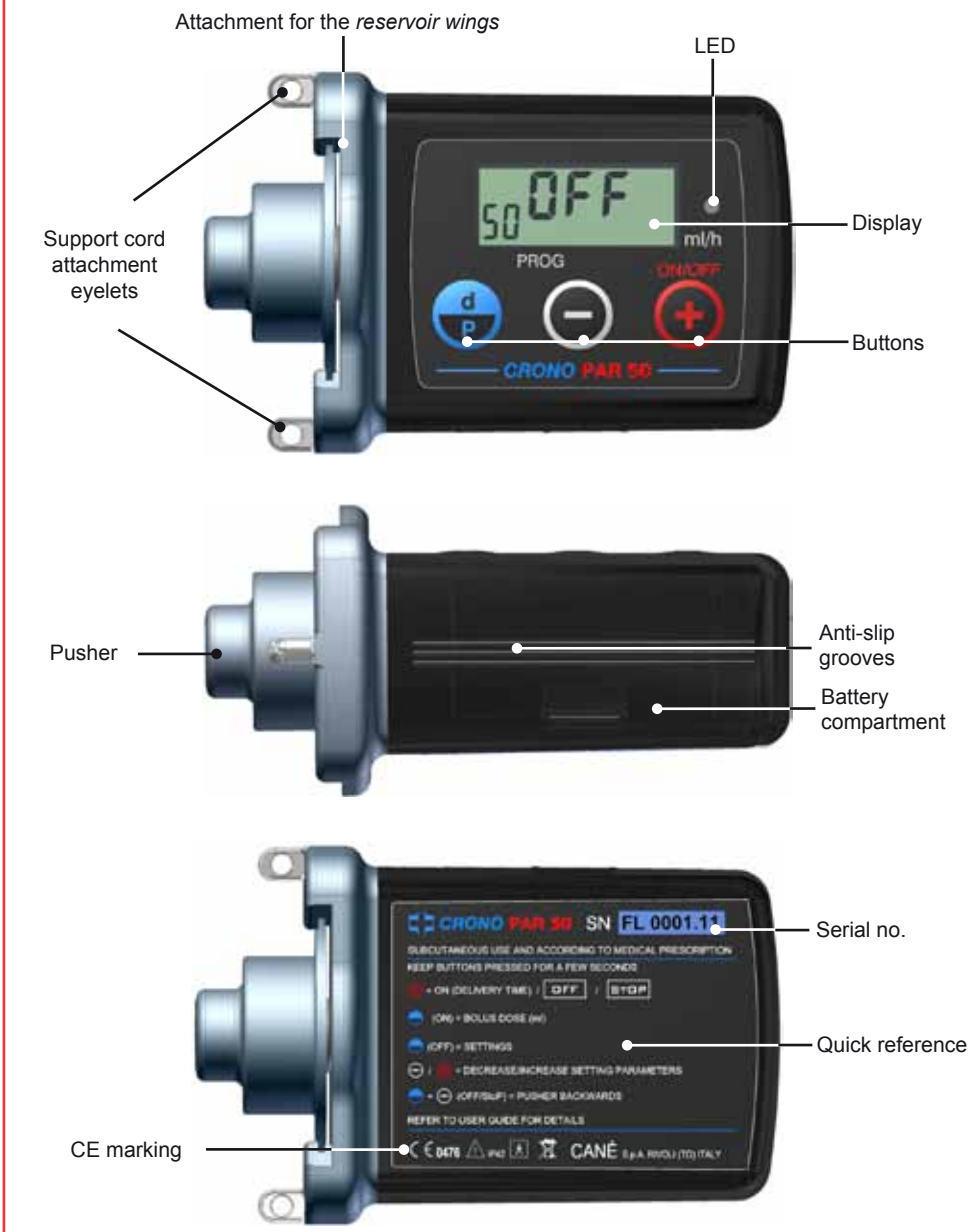
Pump dimensions	3.31 x 2.17 x 1.65 in (84 x 55 x 42 mm).
Weight	4.47 oz. (139 g), including battery.
Battery	Lithium CR 123A 3V (battery life of about 100 infusions).
***Single-use* reservoir**	With a 50 ml capacity and a "*Luer-Lock*" universal security attachment.
Volumes that can be administered	Selectable, from 1 to 50 ml in 1 ml increments.
Flow rates in FrEE mode (F1, F2, F3)	Programmable from: • 0.05 ml/h to 1.00 ml/h in 0.01 ml/h increments • 1.00 ml/h to 3.00 ml/h in 0.02 ml/h increments; • 3.00 ml/h to 5,00 ml/h in 0.05 ml/h increments; • **F2** and **F3** may also be programmed to 0.00 ml/h or to **oFF** (flow rate display disabled).
Selectable flow rates in FrEE mode	3, all programmable.
Flow rates in Auto mode (F1, F2, F3)	Programmable from: • 0.05 ml/h to 1.00 ml/h in 0.01 ml/h increments; • 1.00 ml/h to 3.00 ml/h in 0.02 ml/h increments; • 3.00 ml/h to 5.00 ml/h in 0.05 ml/h increments;
Selectable flow rates in Auto mode	4, of which 3 are programmable and 1 is fixed at 0 ml/h.
Bolus dose volume	Programmable from 0.00 to 2.00 ml in 0.020 ml increments.
Interval between bolus doses	Programmable from: • 5 minutes to 1 hour in 5 minute increments; • 1 hour to 24 hours in 15 minutes increments. It is possible to disable this function by setting **no,Lt** (see page 50 and 73).

Flow rate precision	+/-3%.
Occlusion pressure	3 selectable values; for further information see APPENDICES 4-6. The pump is set to **PL2** (2.2 bar +/-1).
Time needed to signal an occlusion	See Appendix 4.
Post-occlusion bolus	About 1.2 ml (in **PL2** mode).
Electronic circuit	Managed by twin microcontrollers with dedicated software.
Settings memory	All settings are automatically entered in a flash memory which is retained even if the device is left without a battery.
Display	Liquid crystal display (LCD) (dimensions 0.43 x 1.1 in 1.1 x 2.8 cm;).
Motor	Coreless DC motor. The microcontroller controls the rotation speed using an infrared encoder.
Settings lock	Two selectable levels.
Safety circuit	Checks that the device is functioning correctly, intervening in the event of any anomaly with acoustic signals and messages on the display.
Ingress protection rating	IP 42
Pump operating conditions	+10°C / +45°C. 30% / 75% RH. 700 hPa / 1060 hPa.
Pump storage conditions	-10°C / +60°C. 10% / 85% RH. 500 hPa / 1060 hPa.

SUPPLIED STANDARD EQUIPMENT

1. Ambulatory infusion pump with *reservoir* ***CRONO*** **PAR 50**.
2. Infuser carry-case (Code: VAL/04).
3. Elastic belt (Code: CM/01).
4. Collar strap (Code: CM/18D).
5. Fabric case (Code: CM/06).
6. 2 batteries (one of which is already inserted in the pump) (Code: CR/123A).
7. 1 User Guide.
8. Battery-cover opening tool (Code: CA/02).

PUMP PARTS


Attachment for the *reservoir wings*
LED
Support cord attachment eyelets
Display
Buttons
Pusher
Anti-slip grooves
Battery compartment
Serial no.
Quick reference
CE marking
50 OFF
ml/h
PROG
ON/OFF
CRONO PAR 50
SN FL 0001.11
SUBCUTANEOUS USE AND ACCORDING TO MEDICAL PRESCRIPTION
KEEP BUTTONS PRESSED FOR A FEW SECONDS
REFER TO USER GUIDE FOR DETAILS
CANÈ

LED

The red LED on the right of the display activates in the following circumstances:

1 - when the battery is inserted during the pump verification checks, see page 30;

2 - when an error has occurred. For further information, see page 26-27.

CONTROL BUTTONS

There are 3 control buttons.

The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect. Use only your fingertips; do not use sharp objects.

The buttons make a clicking sound when pressed.

A brief beep confirms that a command is being executed.

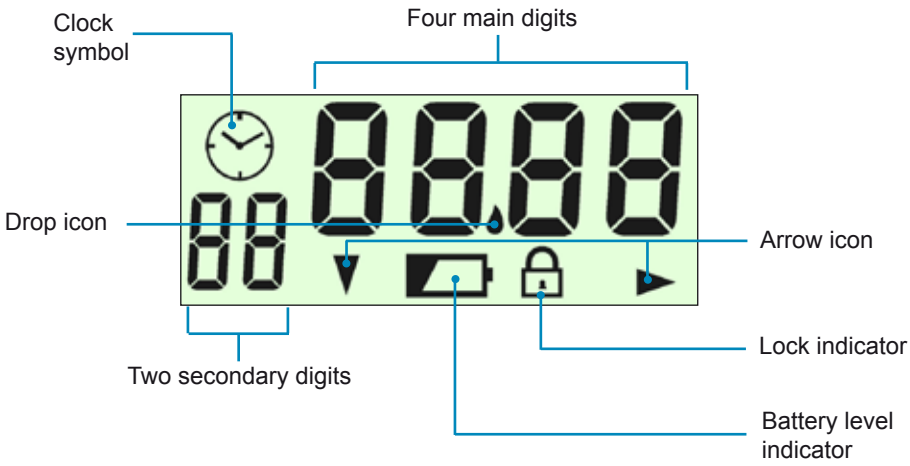
WARNING

The buttons have different functions depending on the condition the pump is in when they are pressed:

- **OFF**
- **StoP**
- **ON**

LIQUID CRYSTAL DISPLAY (LCD)

The liquid crystal display uses text messages and icons to display practical information about the settings, the operation being performed and any error situations.



Four main digits of the display

Display principal information related to the values of the settings, error information, etc.

Two secondary digits of the display

Display one of the following details:

- the size (volume) of the *reservoir*;
- the time (if the **Auto** mode has been selected);
- information related to the setting being displayed in the four main digits;
- The unit of measurement of the setting being displayed.

“Clock” symbol:

Only displayed when **Auto** is selected (see related section on page 53-76). When the clock symbol is visible, the 2 secondary digits below it indicate the current hour of the 24-hour treatment period (in **OFF** or **StoP**) or the set flow (in **ON**).

“Low Battery” indicator:

Displayed when the battery is nearly spent (see related section on page 21).

“Drop” icon:

Steady: it separates integers from decimal numbers.
Flashing: the hour and minute separator.

“Arrow” icon:

- a downward arrow indicates that the pump is being programmed;
- A right arrow indicates that the setting shown is expressed in ml/h.

“Minute” indicator:

- flashes when the remaining delivery time is expressed in minutes (time left is less than 60 minutes);
- displayed (steady) when the interval between two bolus doses is expressed in minutes.

“Lock” indicator:

Indicates that the settings are locked (**L1**); i.e. they can be viewed but cannot be changed (except the time).

LOW BATTERY ALERT

The appearance of the "**LOW BATTERY**" alert (not flashing) on the display indicates that the battery is nearly spent.

If the alert remains displayed for several consecutive infusions, the "**SPENT BATTERY**" message is displayed, accompanied by a beep repeated about every 10 seconds. In these circumstances the pump can no longer be used and the battery must be replaced.

WARNINGS

• You are advised to replace the battery after the "**LOW BATTERY**" alert is displayed.

• The battery must not be replaced:
- during an infusion;
- with the infusion set connected to the patient.

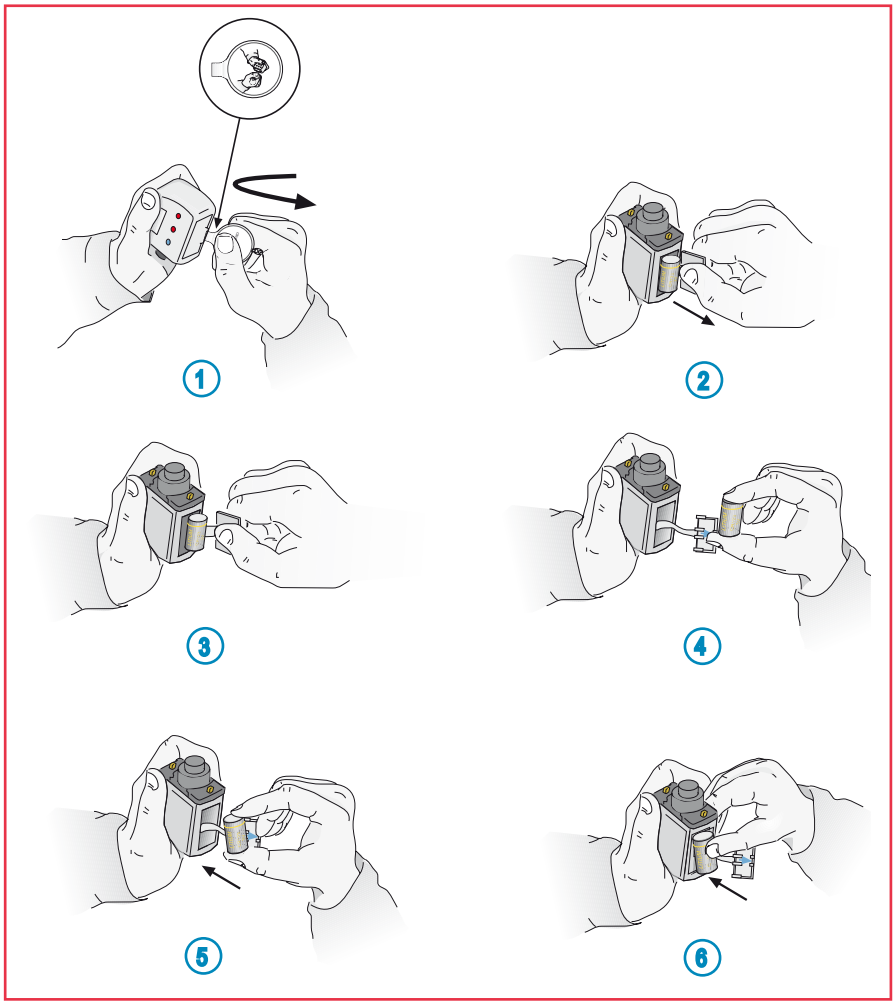
BATTERY REPLACEMENT

Use a 3 Volt Lithium battery, model CR 123A.
To replace the battery, ensure that the pump is switched off (the display shows **OFF** or **StoP**), and then proceed as follows:

1. open the cover of the battery compartment with the appropriate tool supplied, or by using a paper clip;
2. pull back the cover;
3. use the small ribbon strap (which lies under the battery) to facilitate removal of the battery;
4. remove the discharged battery and discard it properly, using the appropriate containers.

5. wait 10 seconds before inserting the new battery checking that it is in the correct position and that the ribbon strap is under the battery;

6. after you have inserted the battery, close the cover.



In the event that it is not possible to remove the battery using the ribbon strap, do not use an object to lever out the battery, but proceed as follows:

• hold the pump and the compartment cover firmly in your one hand;

• strike the palm of your other hand with the pump, to jolt the battery from the compartment.

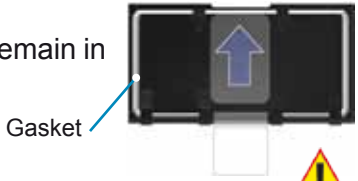
NOTES

• After you have inserted the battery, the pump runs a self-diagnosis test during which it will emit brief audio signals and display all of the icons and indicators.

• During the battery replacement, the pump retains the current settings in its memory.

• Ensure that the battery compartment cover is closed correctly.

• The cover is supplied with a gasket which must remain in position as indicated in the illustration.



WARNINGS

- Do not use rechargeable batteries.
- Using other types of battery than lithium CR 123A batteries could cause the pump to malfunction.
- The battery life can be influenced by the age of the battery and the temperature and circumstances of its use and storage.
- Ensure you always have a replacement battery available for use.
- If the pump is left inactive for long periods (1-2 months or more), you are advised to remove the battery.

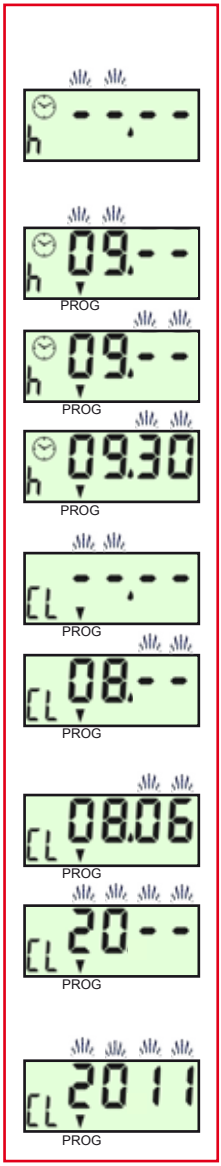
- The time remains in the memory for about 36 hours even when there are no batteries in the device. After 36 hours have elapsed, when the battery is inserted the display will show dashes on the main digits, and the following must be set: **hours**, **minutes, day**, **month** and **year** by pressing the − or + buttons.

By subsequently pressing the button it is possible to display the two flashing dashes on the right of the drop, representing the **minutes**.

By pressing the button once more, it is possible to set the date with the two flashing dashes displayed on the left, which represent **the day.**

By pressing the button once more, it is possible to display the two flashing dashes on the right, which represent **the month.**

By pressing the button once more, it is possible to display the two digits and flashing dashes, which represent **the year.**



SETTINGS LOCK

The ***CRONO*** **PAR 50** pump has 2 access configurations:

- **L0 (unlocked)**: in this configuration you can use the control buttons to access all of the settings and parameters, and control all of the operational functions;

- **L1 (locked)**: in this configuration you can use the control buttons to control the operational functions, except for the time. When the pump is set to **L1** the display shows the lock indicator (indicator displayed).
Before attempting to modify any of the settings, ensure that the selected access level of the pump is **L0** (indicator not displayed).

To lock or unlock the settings, do the following:

1. with the pump set to either **OFF** or **StoP**, press the button for about 6 seconds: the display shows the number of bolus doses administered during the last infusion, followed by the number of infusions that have been completed;

2. without releasing the button, also press the button: the display shows either **L0** or **L1**, with **0** or **1** flashing;

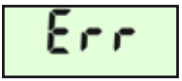
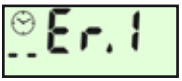
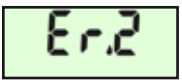
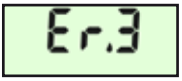
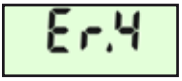
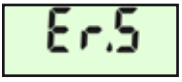
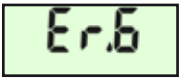
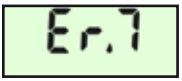
3. you can now select whether to lock or unlock the settings by pressing either or .

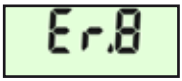
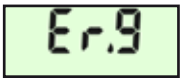
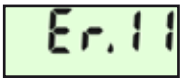
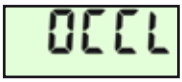
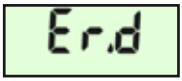
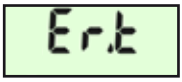
WARNINGS

• This settings access level (**L0** and **L1**) remains in memory even if the battery is removed.

• When the settings access is **L1** (locked), any attempt to access the locked options will cause the pump to beep intermittently and display the "lock" indicator.

ERRORS AND ANOMALIES

DISPLAY	AUDIBLE SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
	Brief continuous audible signal.	Operation not allowed.	---
	Beep repeated every 10 sec approximately.	Possible hardware anomaly of the clock (only **Auto** mode).	Press the ⊕ button; see warnings on page 28.
	Continuous acoustic signal and flashing LED.	Critical problem in the safety system.	Press the ⊕ button
	Beep repeated every 10 sec approximately.	Anomaly in the motor circuit.	Press the ⊕ button
	Beep repeated every 10 sec approximately.	Mechanism of the pusher blocked while withdrawing (could be caused by a foreign body preventing its movement).	Eliminate the cause and initialise the pump (see page 30).
	Beep repeated every 10 sec approximately.	Pusher system blocked.	Press the ⊕ button
	Beep repeated every 10 sec approximately.	Motor anomaly.	Initialise the device (see page 30).
	Intermittent acoustic signal repeated approximately every 10 seconds (possibly accompanied by flashing LED).	Communication error between the two microcontrollers.	Press the ⊕ button

DISPLAY	AUDIBLE SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
	Beep repeated every 10 sec approximately.	When a battery is inserted and at the start of every infusion, the device runs a control algorithm on the parameters stored in the memory. If an error is found, the manufacturer default settings are restored, the motor stops and an error is shown on the display.	Initialise the device (see page 30) and set the prescribed infusion parameters.
	Beep repeated every 10 sec approximately.	Anomaly in the safety circuit which drives the pump motor. If an error is found, the pump locks and the error is indicated.	Initialise the device (see page 30).
	Beep repeated every 10 sec approximately.	Anomaly in the pusher system.	Initialise the device (see page 30).
	Beep repeated every 10 sec approximately.	Mechanism blocked because of an occlusion in the infusion line.	Eliminate the cause and press the button (see page 29).
	Beep when you press the button.	The bolus dose has been set to 0.00 ml.	This function is not available. (see pages 50 and 73).
	Beep when you press the button.	The bolus dose cannot be administered because the dose interval imposed by the function has not been completed.	This function is not available. (see pages 50 and 73).

NOTE

The displayed error messages (from **Er,1** to **Er,11** and **OCCL**) are accompanied by an acoustic signal and the system stops.

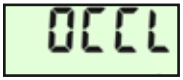
WARNINGS

• Following the display of error message **Er,1** in the:
- **ON** condition (**Auto** version) after you press the button, the pump recommences the delivery of the drug, but only using the lowest of the programmed flow rates;
- **OFF** condition, after you press the button, the pump will be set back to **OFF**;
- **Battery insertion** condition, after you press the button, the pump will be initialised (as described on page 30).
• The display will show the clock icon and the flashing dashes on the two secondary digits until the time is reset.
• It is necessary to reset the hours and minutes by accessing the settings as described in the "**PUMP SETTINGS SEQUENCE**" section on pages 38 and 59.
• If at the time when **Er,1** is signalled the hourly flow value is set to **F0**, the pump will **NOT** administer the drug until it is switched off and on again.
• If the time is not reset, every time the pump starts or resumes an infusion, it will signal **Er,1** and administer the drug for the whole delivery time at the minimum flow among the 3 set values.
• In the event that it is not possible to reset the time from the settings menu of the pump, contact the CANÈ S.p.A. Technical Support Service.
• Error messages **Er,2** and **Er,7** are accompanied by the flashing red LED.
• Following the display of error message **Er,8** and the successive initialisation, the system re-imposes the factory settings in **FrEE** mode (see pages 32 and 53): in this event the pump settings prescribed by the doctor should be re-entered.
• The settings prescribed by the doctor must be noted on a copy of the patient settings record sheet on page 110 or the notes sheet on page 113.

INFUSION SET OCCLUSION

The pump is designed to recognise when the administration of a drug has been interrupted by external means, such as, for example, the kinking of the infusion set tube and the consequent occlusion.

In these circumstances, the pump stops the infusion: the display indicates that there is an occlusion, accompanied by a brief beep. The pump then continues beeping every 10 seconds.



While the system is still occluded, the drug is not administered: to recommence the infusion, press the button after having removed the cause of the occlusion.

NOTES

- The cause of the occlusion is to be found along the infusion line and at the point of injection.
- To avoid or reduce the incidence of occlusions, you are advised to use an infusion set with *anti-kinking* tubes.

POST-OCCLUSION BOLUS

The occlusion alarm is given when the pump detects excessive back pressure in the infusion line. This back pressure must be removed without releasing a post-occlusion bolus, which could cause serious harm to the patient.

The volume of a ***CRONO*** **PAR 50**, post-occlusion bolus, considering only the combined volume of the pump and the *reservoir* is about 0.9 ml (in **PL2** mode).

WARNINGS

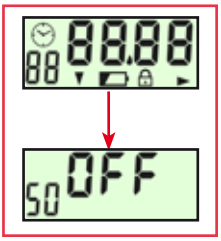
- The volume of the bolus released after an occlusion can vary, depending on the infusion set and all the other components that comprise the infusion line.
- Another element that could affect the volume of the released bolus after an occlusion is the presence of any air in the system.
- After the occlusion alarm is given, take any and all measures appropriate to avoid the administration of a post-occlusion bolus, such as, for example, disconnecting the infusion set from the patient.

PUMP INITIALISATION

When you insert the battery, the pump runs the initialisation sequence, during which it:

1. runs a self-diagnosis test, emitting a series of brief acoustic signals, flashing the red LED and displaying all the indicators and icons on the screen;

2. displays **OFF** at the end of the preceding operation.



NOTES

- The pump is supplied with a new battery already inside the pump.
- To initialise the device, remove the battery and reinsert it after 10/15 seconds. If the error is detected again after the corrective action or initialisation of the device, contact the CANÈ S.p.A. Technical Support Service.
- For instructions on how to install the battery, see page 21.
- You are recommended to initialise the pump if it is left unused for a long period (more than 1 - 2 months) and the battery is not removed.
- If, after the insertion of the battery (initialisation of the pump) the display does not indicate the above-mentioned information, you are recommended to remove and re-insert the battery.

SELECTING THE PUMP MODE

The ***CRONO*** **PAR 50** pump offers, in a single body, two programming modes called **FrEE** and **Auto**, to satisfy different therapeutic needs.
FrEE is a mode with basic functions that allows the patient to freely select, during the day, one of the 3 available flow rates pre-programmed by the doctor, the bolus dose and the drug volume contained in the *reservoir*.
Auto is a mode with advanced functions which allows you to program different flow rates over the daily 24-hour period, as well as other functions described below.

To be able to select the mode of the pump, it must:
- be set to **OFF** (at the beginning of a full or partial infusion);
- have the settings lock set to **L0**, ("lock" indicator off).

Procedure:

1 - press the ⊖ button for about 10 seconds, until the display subsequently shows the number of bolus doses administered during the last infusion, the number of completed infusions and finally the **SEt** message;

2 - when the message **SEt** is displayed, release the ⊖ button and press the ⏻. The display shows **Auto** or **FrEE** flashing message and the arrow points to **PROG** demonstrating that the pump is ready to be programmed;

3 - press the ⊖ button to switch from **Auto** to **FrEE**, or press the ⊕ button to switch from **FrEE** to **Auto**;

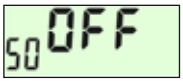
4 - if you have set **FrEE** go to the next page. If you have set **Auto** go to page 53.

WARNINGS

- Always verify that the clock is correctly set when switching pump mode from **FrEE** to **Auto**.

- When the device is set to **StoP** it is not possible to change the pump mode, and the pump displays **Err**.

SELECTED PUMP MODE: FrEE



FACTORY SETTINGS

The pump is supplied with the following default settings:

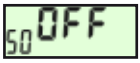
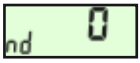
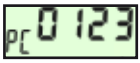
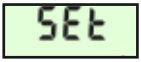
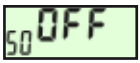
Dose	0.20 ml
Interval between doses	**no,Lt**
Flow rate 1	0.50 ml/h (**F1**)
Flow rate 2	**oFF** (**F2**)
Flow rate 3	**oFF** (**F3**)
Volume	50 cc
Number of administered bolus doses	0
Number of infusions	0
Access level (settings lock)	**L0**
Occlusion pressure	**PL2** (2,2 bar +/-1)

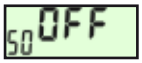
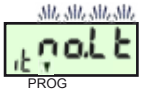
QUICK REFERENCE FrEE

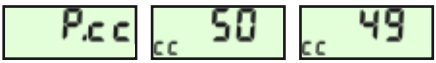
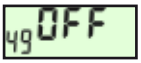
The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect.

WARNING

These quick reference instructions are not an alternative to reading the information in this manual, but give a basic and rapid summary of the pump's functions.

	BUTTONS	SELECTING THE PUMP MODE	DISPLAY
PUMP SET TO OFF		• Pump set to **OFF**	
	 (keep pressed)	• Number of bolus doses administered during the last infusion (after 2 seconds)	
		• Displaying the number of infusions (after 6 seconds)	
		• Pump mode selection (after 10 seconds)	
		• Accessing the pump mode selection	
		• Selecting the pump mode (**FrEE**/**Auto**)	 PROG
		• Pump set to **OFF**	

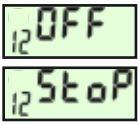
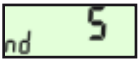
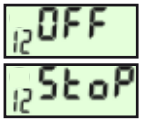
	BUTTONS	CONFIGURING THE SETTINGS IN THE OFF CONDITION	DISPLAY
PUMP SET TO OFF		• Pump set to **OFF**	
		• Set bolus dose volume (from 0.00 to 2.00 ml)	
		• Setting the interval between the bolus doses (from “**no,Lt**” to 24 hours)	
		• Setting the flow rate **F1** (0.05 to 5.00)	
		• Setting the flow rate **F2** (0.00 to 5.00 - oFF - disabled)	
		• Setting the flow rate **F3** (0.00 to 5.00 - oFF - disabled)	
		• Setting the partial volume (from 1 to 50 ml) (see table **SETTING THE PARTIAL VOLUME**)	
		• Pump set to **OFF**	
		• Decrease/increase stored value	

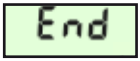
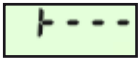
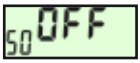
	BUTTONS	SETTING THE PARTIAL VOLUME	DISPLAY
PUMP SET TO OFF		• Setting the partial volume	
		• Decrease/Increase of partial volume	
		• Positioning pusher to partial volume	
		• Pump set to **OFF**	

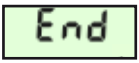
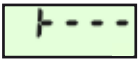
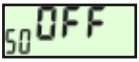
	BUTTONS	SWITCHING ON / *PRIMING*	DISPLAY
PUMP SET TO OFF		• Pump set to **OFF**	SO OFF
		• Priming *function*	Pr
	 (keep pressed)	• Priming function (1.5ml available)	Pr 0.56
		• Pump in **OFF** (prime delivered, prime function still available see pages 45/46)	Pr OFF
		• Switching on the pump	F1 On
		• Start of infusion	F1 98.52
		• Selecting the flow rate	F1 0.50 ml/h PROG

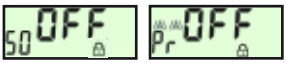
	BUTTONS	ADMINISTRATION OF BOLUS DOSE	DISPLAY
PUMP ON		• Pump set to **ON**	F1 4.00
		• Administration of bolus dose	d 0.25
		• Pump set to **ON**	F1 3.58

	BUTTONS	SWITCHING OFF/StoP	DISPLAY
PUMP ON		• Delivery time	F1 4.00
		• Pump set to **StoP**	SO StoP
		• Silence buzzer and stop display flashing	SO StoP

	BUTTONS	SETTINGS LOCK	DISPLAY
PUMP SET TO OFF/StoP		• Pump set to **OFF** or **StoP**	
	(2 secs.)	• Displaying the number of administered bolus doses	
	(5 secs.)	• The number of completed infusions is displayed	
	press and hold	• Access settings lock	 
	/	• Settings lock selection/deselection	
		• Pump set to **OFF** or **StoP**	 

	BUTTONS	WITHDRAWAL OF THE PUSHER BEFORE THE END OF THE INFUSION	DISPLAY
PUMP ON		• Pump set to **StoP**	
	+	• Pump set to **End**	
		• Withdrawal of the pusher	
		• Pump set to **OFF**	

	BUTTONS	END OF INFUSION	DISPLAY
PUMP ON		• Pump set to **End**	
		• Withdrawal of the pusher	
		• Pump set to **OFF**	

	BUTTONS	DISPLAYING	DISPLAY
PUMP SET TO OFF/StoP - L1		• Pump in **OFF**	
		• Bolus dose volume	
		• Interval between the bolus doses	
		• Flow rate **F1**	
		• Flow rate **F2**	
		• Flow rate **F3**	
		• Partial volume	
		• Pump in **OFF**	

PUMP SETTINGS SEQUENCE WITH THE PUMP SET TO OFF OR StoP

To change the settings the pump must:

- be set to **OFF or StoP**;
- have the settings lock off (i.e. set to **L0**).

SETTING THE BOLUS DOSE VOLUME

The bolus dose volume can be set from 0.00 to 2.00 ml in increments of 0.022 ml.

Proceed as follows:

1. with the pump set to **OFF** or **StoP** press the button for a few seconds: the display shows the flashing **BOLUS DOSE VOLUME** indication;

2. to change the value, within 20 seconds press the button to decrease it, or the button to increase it. Each change is indicated by a beep;

3. if you do not press any button for 20 seconds, the settings session is terminated and the message **OFF** or **StoP** is displayed;

4. press the button before the **OFF** or **StoP** is displayed (while the bolus dose volume is still flashing) to continue to the setting of the next parameter: **SETTING THE INTERVAL BETWEEN BOLUS DOSES.**

NOTES

- If you keep either the or button pressed, it is possible to quickly change the bolus dose volume.
- The bolus dose setting is automatically stored in the pump's memory.
- If you press the button when the display indicates **d0,02**, the value changes to **d0,00**: this setting disables the bolus dose function.
- If the settings lock is set to **L1** (the display is showing the "lock" indicator), when you press the button, the pump displays the current settings, which cannot be changed.

WARNING

If the bolus dose volume is set to 0.00 ml, pressing the button during the infusion will display the **Er,d** error message.

SETTING THE INTERVAL BETWEEN BOLUS DOSES

The interval between bolus doses can be set to a value between **no,Lt** (function disabled) and 24 hours, in the following ways:

- from 5 minutes to 1 hour in increments of 5 minutes;
- from 1 hour to 24 hours in increments of 15 minutes.

This applies a temporal limit to the bolus dose function.

Proceed as follows:

1. the display shows the flashing value of the bolus dose interval;

2. press the ⊕ button to increase the value; press the ⊖ button to decrease it. Each change is indicated by a beep;

3. if you do not press any button for 20 seconds, the settings session is terminated and the message **OFF** or **StoP** is displayed;

4. press the ⏻ button before the **OFF** or **StoP** indication is displayed (while the bolus dose interval is still flashing) to continue to the setting of the next parameter: **SETTING THE FIRST FLOW RATE (F1)**.

NOTES

- If you keep either the ⊖ or ⊕ button pressed, it is possible to quickly change the interval between the bolus doses.
- The bolus dose interval setting is automatically stored in the pump's memory.
- Press the ⊖ button with the display showing **it 5',** the display changes to **no,Lt**: this setting disables the function that regulates the interval between bolus doses, and thus disables any time restrictions on the administration of bolus doses.

SETTING THE FIRST FLOW RATE (F1)

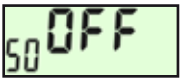
The flow rate can be set from 0.05 to 5.00 ml/h as follows:
- from 0.05 ml/h to 1.00 ml/h in increments of 0.01 ml/h;
- from 1.00 ml/h to 3.00 ml/h in increments of 0.02 ml/h;
- from 3.00 ml/h to 5.00 ml/h in increments of 0.05 ml/h.

Proceed as follows:

1. the display shows the flashing value of the first flow rate;

2. press the ⊕ button to increase the value; press the ⊖ button to decrease it. Each change is indicated by a beep;

3. if you do not press any button for 20 seconds, the settings session is terminated and the message **OFF** or **StoP** is displayed;



4. press the PROG button before the **OFF** or **StoP** indication is displayed (while the **F1** flow rate value is still flashing) to continue to the setting of the next parameter: **SETTING THE SECOND FLOW RATE (F2)**.

NOTES

- If you keep either the ⊖ or ⊕ button pressed, it is possible to change the flow rate quickly.

- Every flow rate setting is automatically stored in the pump's memory.

SETTING THE SECOND AND THIRD FLOW RATES (F2 AND F3)

The flow rate can be set from 0.00 to 5.00 ml/h as follows:
- from 0.00 ml/h to 1.00 ml/h in increments of 0.01 ml/h;
- from 1.00 ml/h to 3.00 ml/h in increments of 0.02 ml/h;
- from 3.00 ml/h to 5.00 ml/h in increments of 0.05 ml/h.

The second and third flow rates are set in the same manner as the first.

After you have set the third flow, press the button before the **OFF** or **StoP** indication is displayed (while the **F3** hourly flows value is still flashing) to continue to the setting of the next parameter: **PARTIAL VOLUME**.

NOTES

- If you keep either the or button pressed, it is possible to change the flow rate quickly.

- If the flow rate is programmed to 0.00 ml/h, the device will not administer the drug via flow, but only through the administration of bolus doses.

- it is also possible to set the **oFF** condition for flows **F2** and/or **F3**, so that the flows will not be displayed, and therefore will not be selectable, when the pump is **ON**.

SETTING THE PARTIAL VOLUME

The partial volume function is used when the treatment requires an infusion with less than 50 ml.

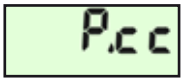
The partial volume can be set from 1 cc to 50 cc in increments of 1 cc.
To set this parameter, press the button again.
The partial volume function can only be set before starting a new infusion, either a complete one (50 ml) or a partial one.

Proceed as follows:

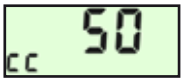
1. the display shows a flashing value for the volume, preceded by **cc** , which indicates the unit of volume (1 cc = 1 ml);

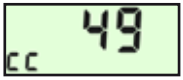
2. press the button to decrease the value, and the button to increase it. Each change is indicated by a beep;

3. do not press any button for 20 seconds and the setting phase will end. The display will show **P,cc**. Press the button while **P,cc** is shown to cancel the partial volume setting. The display shows the **OFF** indication;

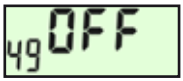


4. the pump moves the pusher to the position which corresponds to the set volume: an intermittent acoustic signal is emitted while it does so, and the pump displays - in real time - the actual volume corresponding to the pusher position;





5. when the pusher is in the correct position, the display shows **OFF**. The selected partial volume value will be shown on the secondary display.



NOTES

• The partial volume setting is automatically stored in the pump's memory.

• At the end of the infusion, the pusher returns to the position corresponding to the partial volume setting.

• The partial volume setting can be interrupted by pressing the ⊕ button: the pump switches off (the display shows **OFF** or **StoP**) and the pusher, if it was moving forward, remains where it was when the interruption occurred. The partial volume setting is not stored and the previous value remains in memory. If, however, the pusher was in the process of being withdrawn, the display shows **OFF** and **P,cc alternately.** The only possible operation is to continue the withdrawal of the pusher, by pressing the ⊕ button. The pusher withdraws to the position of the partial volume settings.

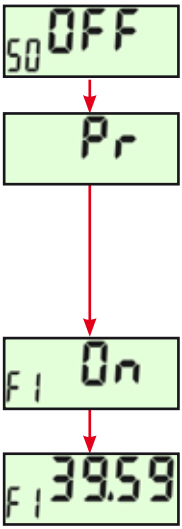
• When the device is set to **StoP** it is not possible to change the partial volume, and the pump displays **Err**.

WARNINGS

- This operation must not be carried out with the infusion set connected to the patient.
- A partial volume cannot be set while an infusion is in progress.
- The partial volume setting remains in the pump's memory even if the battery is removed.
- If the battery is removed when the pump is set to **OFF**, the partial volume remains in memory and the pusher is not withdrawn.
- If the battery is removed when the pump is set to **ON**, the pusher returns to the infusion start position for recalibration, and then repositions itself at the stored partial volume.

SWITCHING ON THE PUMP

From the **OFF** condition, press the ⊕ button and the pump will give a brief beep and display the following in sequence:



• **Pr** (priming *function*);
There are three options:

a. postpone the *priming*;
b. cancel the *priming*;
c. perform the *priming*.

• **switching on the pump and displaying the set flow;**

• **delivery time and flow value display.**

WARNINGS

Before starting an infusion:

• check that the *reservoir* is correctly connected;

• inspect the infusion line to ensure there are no folds, *clamps* or other occlusions in the line;

• expel any air bubbles.

PRIMING THE INFUSION LINE

The *priming* function allows for filling the infusion line with the drug contained in the reservoir.

The volume available for *priming* is 1.5 ml.

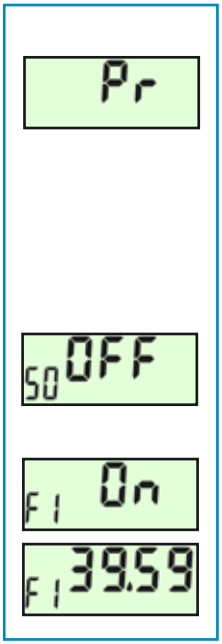
The *priming* function is enabled when the device is switched on and the pusher is in the infusion start position, regardless of whether the settings lock is on.

The *priming* procedure is as follows:

1. switch on the device as described in the relevant section;

2. the display shows **Pr**. There are three options:

a. postpone the *priming*;
b. cancel the *priming*;
c. perform the *priming*.



a. Postpone the *priming*

Press the ⊖ and ⊕ buttons together: the pump switches off and the display shows **OFF**. Or wait 10 seconds and the pump switches itself off automatically.

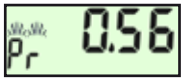
b. Cancel the *priming*

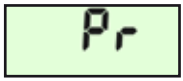
Press the ⊕ button; the pump begins the infusion and the display shows the time remaining until the end of the infusion.

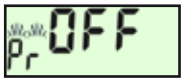
c. Perform the *priming*

Press and hold down the button to deliver the *priming dose;* the *priming* function can be interrupted by releasing the button. The display shows a flashing letter **Pr** followed by the number of millilitres delivered. The display then shows **Pr** again. In this way it is again possible to postpone, cancel or perform the *priming* function. The procedure can be repeated until a maximum of 1.5 ml has been delivered in total.

At the end of this phase, if the infusion is not started by pressing the button, the pump returns to **OFF.**







NOTES

• Every time the pump administers 0.5 ml of drug, it emits an audible signal and pauses for about one second.

• Continue with the priming until the drug arrives at the end of the infusion set.

• If, after the *priming* indication is displayed, the buttons are not pressed again for 10 seconds, the display shows **OFF**.

WARNINGS

• Do not *prime* the infusion set with the tube connected to the patient.

• The *priming* function must only be performed with the *reservoir* attached to the infusion set and before inserting the needle into the infusion site.

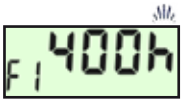
• Before beginning an infusion, check that there are no air bubbles in the infusion line, expelling any that are found. Alternatively, use a vented filter.

• While the displays flashes **Pr** it is not possible to select the programming mode (**FrEE**/**Auto**) or change the partial volume.

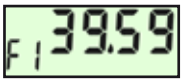
PUMP SWITCHED ON

When the pump is in ON condition, the display shows the delivery time in:

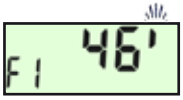
- hours with a flashing **h**;



- hours and minutes, with the "drop" icon flashing;



- minutes, if the time to go is less than one hour, with the "minutes" indicator flashing.



If a flow rate of 0.00 ml/h has been set, the display shows **F0,00** with a flashing letter **F**; In this event the drug can only be administered by means of a bolus dose request.

NOTE

If the device is switched off during an infusion and the display shows **StoP**, press the + button to restart the infusion.

SELECTING THE FLOW RATE

This function allows the patients to change the flow during the day based on their demands, choosing among the 3 available flow rates pre-programmed by the doctor.

Procedure:

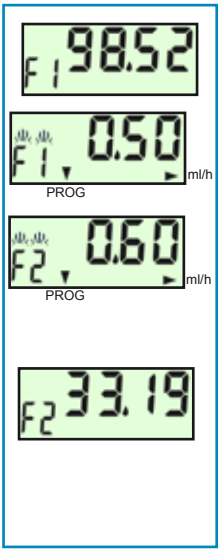
1 - with the pump on, press the ⊖ button;

2 - the display shows the currently set flow rate flashing with the arrow indicating the programming mode;

3 - press the ⊖ button again, and the display shows the other available flow values;

4 - after selecting the desired flow, do not press the ⊖ button again, and after a few seconds the value is saved in the memory and the pump will proceed with the infusion at the newly selected flow rate;

5 - during this selection the and ⊕ buttons are disabled.



NOTES

• If **F2** and/or **F3** are set to **0.00**, the pump allows the selection of these flow values as an alternative to **F1**, with no administering being performed as the flow is equal to **0**; selecting a **0** flow can be convenient to intentionally interrupt the administration for a set period, for instance during the night.
• If **F2** and **F3** are set to **oFF**, the pump allows the display and use of the **F1** flow only.

WARNING

The preset flow selection function is available even when the settings lock is on; to disable this option, it is necessary to set the **F2** and **F3** flows to **oFF** in order to disable them, forcing the pump to use a unique flow rate.

BOLUS DOSE

The bolus is a supplementary dose of the drug that the patient can request when it is needed.
If the bolus dose volume has been set to 0.00 ml, the bolus dose cannot be administered.

Administration of bolus doses

Bolus doses can only be administered while the pump is in **ON** condition.

The procedure for the administration of a bolus dose is as follows:

1. press the button: the pump gives a beep and commences to administer the bolus dose, during which a flashing letter **d** is shown on the secondary display**,** while the volume of the bolus dose being administered is shown on the main display. During the bolus dose administration, the pump beeps and pauses for about 1 seconds for every 0.11 ml of drug administered;

2. at the end of the bolus dose administration, the pump beeps and the display shows the time remaining of the original infusion, or, if the setting is for a flow rate of 0.00 ml/h, it shows **F0,00**.

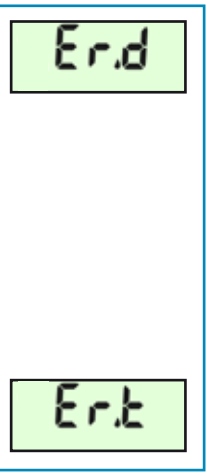
NOTES

• The bolus dose administration can be interrupted by pressing the button.

• If the bolus dose volume is set to 0.00 ml, pressing the button will display the **Er,d** error message.

RESTRICTIONS ON THE ADMINISTRATION OF BOLUS DOSES

If the bolus dose volume is set to 0.00 ml, pressing the button will display the **Er,d** error message.



The administration of bolus doses is limited by the **interval between doses** (temporal limitation).

By setting **no,Lt** you can disable this limitation.

Bolus doses cannot be administered during the interval period observed by the function.

During the limitation period, if you request a bolus dose, the display shows **Er,t** (temporal limitation between active bolus doses).

DISPLAYING THE NUMBER OF ADMINISTERED BOLUS DOSES DURING AN INFUSION AND THE NUMBER OF INFUSIONS

1 - To check the number of bolus doses administered by the patient during an infusion while the pump is in **OFF** or **StoP**, press and hold the button for a few seconds and the value will be displayed.

2 - To check the number of infusions delivered by the device while it is **OFF** or **StoP**, press and hold the button for about 8 seconds.

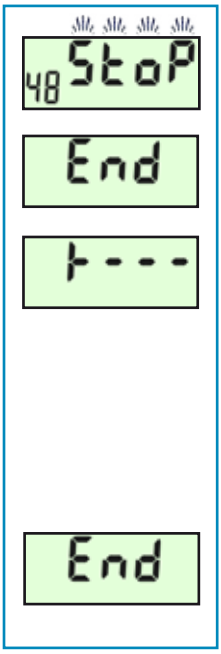
WARNINGS

• The number of the administered bolus doses is only available until the beginning of a new infusion; switching the pump on for a new infusion automatically resets the value.

• The number of bolus doses includes those interrupted by pressing the button.

WITHDRAWING THE PUSHER

1. Withdrawal of the pusher before the end of the infusion
This function allows the interruption of an active infusion, withdrawing the pusher to the start position of the infusion.
To stop an active infusion, do the following:



• switch the pump off by pressing the button;

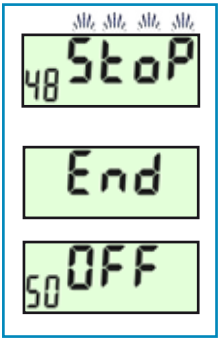
• press the and buttons together: the display shows **End** for 10 seconds and then begins to withdraw the pusher;

• during the 10 seconds that the display shows **End** you can cancel the withdrawal request by pressing the button.

2. Withdrawal of the pusher at the end of the infusion
Ten minutes before the end of the infusion, the device gives an intermittent beep for 2 seconds. This signal is repeated twice at 5 minutes from the end of the infusion.

At the end of the infusion an audible signal is given and the display shows **End**.
After a few seconds, the pusher starts withdrawing until it reaches the start position of the infusion.

NOTES

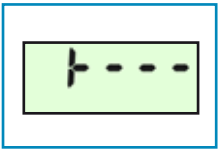


• While the display shows **End**, the withdrawal function can be cancelled by pressing the button. The display shows **StoP**.

• The withdrawal function can be interrupted by pressing the button. The display then alternates between **End** and **OFF**. At this point the only active button is the button. When you press again the pump recommences the withdrawal of the pusher.

Pusher in motion

While the pusher is in a continuous withdrawal motion, the display shows the "**pusher continuous withdrawal**" indication.



NOTE

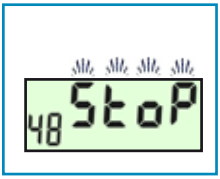
The pusher withdrawal time for a 50 ml volume is approx 6 minutes, and is proportionately less for lower volumes.

WARNING

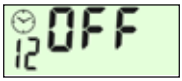
Do not remove the *reservoir* until the pusher has been withdrawn to the infusion start position.

SWITCHING OFF THE PUMP

To switch off the device, press the ⊕ button. The display will show **StoP**. If the pump is switched off during an infusion, the device will emit a series of 10 short beeps every 10 seconds, and the display will flash the **StoP** message. To suppress the audible signals, press the ⊖ button.



SELECTED PUMP MODE: AUTO MODE



FACTORY SETTINGS

The pump is supplied with the following default settings:

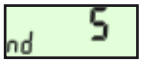
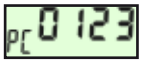
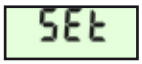
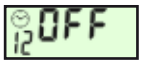
Dose	0.20 ml
Interval between doses	**no,Lt**
Flow rate 1	0.50 ml/h (**F1**)
Flow rate 2	0.50 ml/h (**F2**)
Flow rate 3	0.50 ml/h (**F3**)
Flow rate over 24-hour period	**F2**
Volume	50 cc
Number of administered bolus doses	0
Number of infusions	0
Access level (settings lock)	**L0**

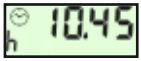
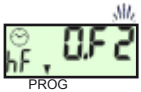
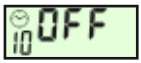
QUICK REFERENCE Auto

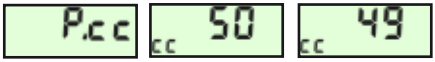
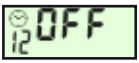
The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect.

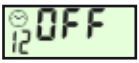
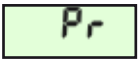
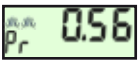
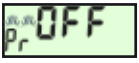
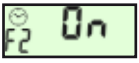
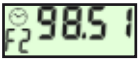
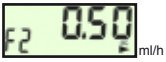
WARNING

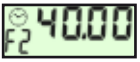
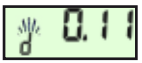
These quick reference instructions are not an alternative to reading the information in this manual, but give a basic and rapid summary of the pump's functions.

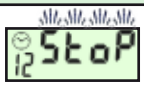
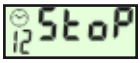
	BUTTONS	SELECTING THE PUMP MODE	DISPLAY
PUMP SET TO OFF		• Pump set to **OFF**	
	 (keep pressed)	• Displaying the number of administered bolus doses (after 2 seconds)	
		• Displaying the number of infusions (after 6 seconds)	
		• Pump mode selection (after 10 seconds)	
		• Accessing the pump mode selection	
		• Selecting the pump mode (**FrEE**/**Auto**)	 PROG
		• Pump set to **OFF**	

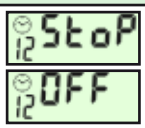
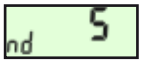
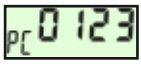
	BUTTONS	SETTINGS	DISPLAY
PUMP SET TO OFF		• Pump set to **OFF** and **L0**	
		• Visualisation of the time	
	 (5 sec)	• Enabling the setting of the time	
		• Set the minutes	
		• Set bolus dose volume (from 0.00 to 2.00 ml)	
		• Setting the interval between the bolus doses (from “**no,Lt**” to 24 hours)	
		• Setting the flow rate **F1** (from 0.05 to 5.00 ml/h)	
		• Set the **F2** flow rate (from 0.05 to 5.00 ml/h)	
		• Set the **F3** flow rate (from 0.05 to 5.00 ml/h)	
	 and	• Assigning the flows over the daily 24-hour period	
		• Setting the partial volume (from 1 to 50 ml) (see table **SETTING THE PARTIAL VOLUME**)	
		• Pump set to **OFF** (after 20 seconds)	
	 /	• Decrease/increase stored value	

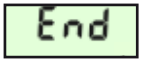
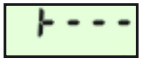
	BUTTONS	SETTING THE PARTIAL VOLUME	DISPLAY
PUMP SET TO OFF		• Setting the partial volume	
	− / +	• Decrease/Increase of partial volume	
		• Positioning pusher to partial volume	
		• Pump set to **OFF**	

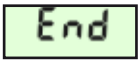
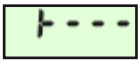
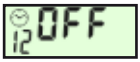
	BUTTONS	SWITCHING ON / *PRIMING*	DISPLAY
PUMP SET TO ON		• Pump set to **OFF**	
	+	• Priming *function*	
	(keep pressed)	• Prime function (1.5ml available)	
		Pump in **OFF** (prime delivered, function still available see pages 70/71)	
	+	• Switching on the pump	
		• Start of infusion	
	−	• Temporary switching between infusion/flow	

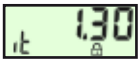
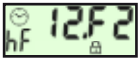
	BUTTONS	ADMINISTRATION OF BOLUS DOSE	DISPLAY
PUMP ON		• Pump set to **ON**	
		• Administration of bolus dose	
		• Pump set to **ON**	

	BUTTONS	StoP	DISPLAY
PUMP ON		• Pump set to **StoP**	
		• Silence buzzer and stop display flashing	

	BUTTONS	SETTINGS LOCK	DISPLAY
PUMP SET TO OFF/StoP		• Pump set to **OFF** or **StoP**	
	 (2 secs.)	• Displaying the number of administered bolus doses	
	 (5 secs.)	• The number of completed infusions is displayed	
	 press and hold	• Access settings lock	
		• Settings lock selection/deselection	
		• Pump set to **OFF** or **StoP**	

	BUTTONS	WITHDRAWAL OF THE PUSHER BEFORE THE END OF THE INFUSION	DISPLAY
PUMP ON		• Pump set to **StoP**	
		• Pump set to **End**	
		• Withdrawal of the pusher	
		• Pump set to **OFF**	

	BUTTONS	END OF INFUSION	DISPLAY
		• Pump set to **End**	
		• Withdrawal of the pusher	
		• Pump set to **OFF**	

	BUTTONS	DISPLAYING	DISPLAY
PUMP SET TO OFF/StoP - L1		• Pump in **OFF** and **L1**	
		• Setting the time see page 61	
		• Bolus dose	
		• Time interval between bolus doses	
		• Flow rate **F1**	
		• Flow rate **F2**	
		• Flow rate **F3**	
		• Flow rates over the daily 24-hour period	
		• Displaying the flows over the daily 24-hour period	
		• Partial volume	
		• Pump in **OFF**	

PUMP SETTINGS SEQUENCE

To change the settings the pump must:
- be set to **OFF** or **StoP**;
- have the settings lock off (i.e. set to **L0**).

You can change the setting while the display is flashing by pressing buttons ⊖ and ⊕.

Visualising/setting the time

To access the settings pres the button for about 4 seconds: the display shows the time.

Pushing the - button for about 5 seconds enables the setting of the time (see page 61).

Setting the minutes

Press the button again, and the display shows and allows setting the **minutes** (see page 61).

Setting the bolus dose volume

Press the button, and the display shows and allows setting of the **bolus dose volume** (see page 62).

Setting the interval between bolus doses

Press the button again, and the display shows and allows setting the **interval between the bolus doses** (see page 63).

Setting the first flow rate (F1)

Press the button again, and the display shows and allows setting the **first flow rate** (see page 64).

Setting the second flow rate (F2)

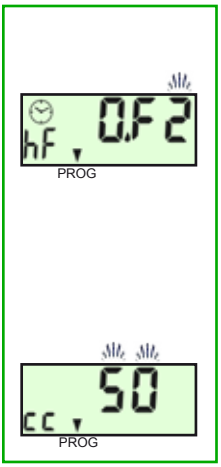
Press the button again, and the display shows and allows setting the **second flow rate** (see page 65).

Setting the third flow rate (F3)

Press the button again, and the display shows and allows setting the **third flow rate** (see page 65).

Assigning the 4 flows over the daily 24-hour period

Press the button again to display and set the assignment of the **4 flows over the daily 24-hour period** (of which one is the fixed **F0** flow, with a rate of 0.00 ml/h). Press the button to scroll the hours (the two digits left of the drop icon) and the button to select the different flows (second digit to the right of the drop icon).



Setting the partial volume

Press the button again to display and set the **partial volume**. **The partial volume can be set only if the pusher is at the infusion start position and the pump is set to OFF.**

NOTES

• If the settings lock is on (set to **L1** with the display showing the lock icon), and you press the button, the device only allows to modify the hours and minutes but not the other parameters, which can, however, be displayed in sequence by pressing the button (see page 78).

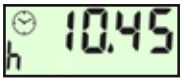
• If the button is pressed when the time is displayed the pump passes directly to the bolus dose setting.

• Do not press any button for 20 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then the **OFF** or **StoP** indication is displayed.

SETTING THE TIME

Proceed as follows:

1. with the pump set to either the **OFF** or **StoP** conditions, press the button for about 4 seconds: the display shows the time;



Pressing the button enables the setting of the time: the hour value begins to flash.

2. press the button to increase the value; press the button to decrease it. Each change in value is indicated by a brief beep;

3. do not press any button for 20 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then the **OFF** or **StoP** indication is displayed;

4. press the button before the **OFF** or **StoP** is displayed (while the hour value is still flashing) to continue to the setting of the minutes;

5. press the button to increase the minutes; press the button to decrease them. Each change in value is indicated by a brief beep;

6. do not press any button for 20 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then the **OFF** or **StoP** indication is displayed.

7. press the button before the **OFF** or **StoP** indication is displayed (while the minutes are still flashing) to continue to the setting of the next parameter: **SETTING THE BOLUS DOSE VOLUME**.

NOTE

If you keep pressing either the or the button, it is possible to quickly change the hours and minutes.

SETTING THE BOLUS DOSE VOLUME

The bolus dose volume can be set from 0.00 to 2.00 ml in increments of 0.022 ml.

Proceed as follows:

1. the letter **d** is shown on the secondary display and the volume of the bolus dose in the primary display. The numeric values are flashing but the **d** is steady;

2. press the ⊕ button to increase the value; press the ⊖ button to decrease it. Each change is indicated by a beep;

3. if you do not press any button for 20 seconds, the settings session is terminated and the message **OFF** or **StoP** is displayed;

4. press the ⏻ button before the **OFF** or **StoP** indication is displayed (while the bolus dose volume is still flashing) to continue to the setting of the next parameter: **SETTING THE INTERVAL BETWEEN BOLUS DOSES**.

NOTES

- If you keep pressing either the ⊖ or ⊕ buttons, it is possible to quickly change the bolus dose volume.
- The bolus dose setting is automatically stored in the pump's memory.
- If you press the ⊖ button when the display indicates **d0,02**, the value changes to **d0,00**: this setting disables the bolus dose function.

WARNING

If the bolus dose volume is set to 0.00 ml, pressing the ⏻ button during the infusion will display the **Er, d** error message.

SETTING THE INTERVAL BETWEEN BOLUS DOSES

The interval between bolus doses can be set to a value between **no,Lt** (function disabled) and 24 hours, in the following ways:

- from 5 minutes to 1 hour in increments of 5 minutes;
- from 1 hour to 24 hours in increments of 15 minutes.

This applies a temporal limit to the bolus dose function.

Proceed as follows:

1. the display shows the flashing value of the bolus dose interval;

2. press the ⊕ button to increase the value; press the ⊖ button to decrease it. Each change is indicated by a beep;

3. if you do not press any button for 20 seconds, the settings session is terminated and the message **OFF** or **StoP** is displayed;

4. press the ⏻ button before the **OFF** or **StoP** indication is displayed (while the bolus dose interval is still flashing) to continue to the setting of the next parameter: **SETTING THE FIRST FLOW RATE (F1)**.

NOTES

- If you keep pressing either the ⊖ or ⊕ buttons, it is possible to quickly change the interval between the bolus doses.

- The bolus dose interval setting is automatically stored in the pump's memory.

- Press the ⊖ button with the display showing **it 5',** the display changes to **no,Lt**: this setting disables the function that regulates the interval between bolus doses, and thus disables any time restrictions on the administration of bolus doses.

SETTING THE FIRST FLOW RATE (F1)

The flow rate can be set from 0.05 to 5.00 ml/h as follows:
- from 0.05 ml/h to 1.00 ml/h in increments of 0.01 ml/h;
- from 1.00 ml/h to 3.00 ml/h in increments of 0.02 ml/h;
- from 3.00 ml/h to 5.00 ml/h in increments of 0.05 ml/h.

Proceed as follows:

1. the display shows the flashing value of the first flow rate;

2. press the ⊕ button to increase the value; press the ⊖ button to decrease it. Each change is indicated by a beep;

3. if you do not press any button for 20 seconds, the settings session is terminated and the message **OFF** or **StoP** is displayed;

4. press the P button before the **OFF** or **StoP** indication is displayed (while the **F1** flow rate value is still flashing) to continue to the setting of the next parameter: **SETTING THE SECOND FLOW RATE (F2)**.

NOTES

- If you keep pressing either the ⊖ or ⊕ buttons, it is possible to change the flow rate quickly.
- Every flow rate setting is automatically stored in the pump's memory.

SETTING THE SECOND AND THIRD FLOW RATES (F2 AND F3)

The second and third flow rates are set in the same manner and within the same limits as the first.

After you have set the third flow, press the button before the **OFF** or **StoP** indication is displayed (while the **F3** hourly flows value is still flashing) to continue to the setting of the next parameter: **ASSIGNING THE FLOWS OVER THE DAILY 24-HOUR PERIOD**.

NOTES

• If you keep pressing either the or buttons, it is possible to change the flow rate quickly.

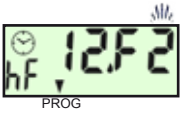
• The flow (**F0**) the value of which is 0.00 ml/h. This flow can be selected only when assigning the flows over the daily 24-hour period.

ASSIGNING THE FLOWS OVER THE DAILY 24-HOUR PERIOD

You can set a different flow rate for every hour of the day, choosing between the four available rates (**F0**, **F1**, **F2**, **F3**).

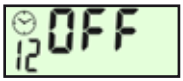
Proceed as follows:

1. the first two digits of the display show the hour of the day (24-hour clock) while the last two show the selected flow for the corresponding hour of the day. The first three digits are steady, but the last numeric digit, after the **F** (0, 1, 2 or 3) indicating the flow, is flashing;



2. press the − button to select the hour of the day; then press the + button to select the required flow corresponding to the selected hour of the day. Each change is indicated by a beep. Press the − button again to change the display to the next hour: press the + button to select the required flow. Proceed in the same way to set the flows for each successive hour;

3. do not press any button for 20 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then the **OFF** or **StoP** indication is displayed;



4. press the P button before the **OFF** or **StoP** indication is displayed (while the hourly flow value is still flashing) to continue to the setting of the next parameter: **SETTING THE PARTIAL VOLUME**.

NOTE

If you set the **F0** flow rate for any hour, during that hour no drug will be administered, as the flow rate will be 0.00 ml/h: the display shows the remaining time of the infusion, and pressing the − button will temporarily display **F0** with the value of 0.00 ml/h.

SETTING THE PARTIAL VOLUME

The partial volume function is used when the treatment requires an infusion with less than 50 ml.

The partial volume can be set from 1 cc to 50 cc in increments of 1 cc. To set this parameter, press the button again.
The partial volume function can only be set before starting a new infusion, either a complete one (50 ml) or a partial one.

Proceed as follows:

1. the display shows a flashing value for the volume, preceded by **cc** , which indicates the unit of volume (1 cc = 1 ml);

2. press the button to decrease the value, and the button to increase it. Each change is indicated by a beep;

3. do not press any button for 20 seconds and the setting phase will end; the display will show **P,cc**;

4. the pump moves the pusher to the position which corresponds to the set volume: an intermittent acoustic signal is emitted while it does so, and the pump displays - in real time - the actual volume corresponding to the pusher position;

5. when the pusher is in the correct position the display shows **OFF**.

NOTES

• The partial volume setting is automatically stored in the pump's memory.

• At the end of the infusion, the pusher returns to the position corresponding to the partial volume setting.

• The partial volume setting can be interrupted by pressing the button: the pump switches off (the display shows **OFF** or **StoP**) and the pusher, if it was moving forward, remains where it was when the interruption occurred: the partial volume setting is not stored and the previous value remains in memory. However, if the pusher was withdrawing: the display toggles between **OFF** and **P,cc.** The only possible operation is to continue the withdrawal of the pusher, by pressing the button. The pusher withdraws to the position of the partial volume settings.

• When the device is set to **StoP** it is not possible to change the partial volume, and the pump displays **Err**.

WARNINGS

• This operation must not be carried out with the infusion set connected to the patient.

• A partial volume cannot be set while an infusion is in progress.

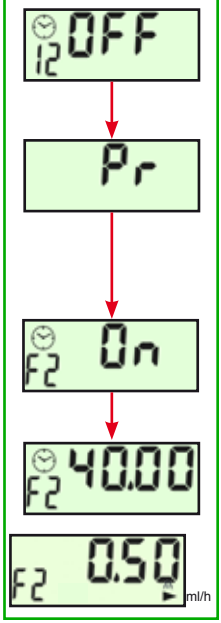
• The partial volume setting remains in the pump's memory even if the battery is removed.

• If the battery is removed when the pump is set to **OFF**, the partial volume remains in memory and the pusher is not withdrawn.

• If the battery is removed when the device is in the **ON**, the pusher returns to the infusion start position after a reset and then repositions itself according to the memorised partial volume.

SWITCHING ON THE PUMP

From the **OFF** condition, press the ⊕ button. The pump will give a brief beep and display:



• **Pr** (priming *function*)
There are three options:

a. postpone the *priming*;
b. cancel the *priming*;
c. perform the *priming*.

• **Switching on the pump**

• After you have performed the *priming,* or if you switch the pump on when it is in the **StoP** condition, the display shows the infusion time in hours or in hours and/or minutes or just minutes.
Press the ⊖ button again, and the display shows the corresponding hourly flow value.

NOTE

During the infusion the time shown on the display is counted down:
• hour by hour if the time shown on the display is expressed in hours, with a flashing letter **h**;

• minute by minute if the time shown on the display is expressed in hours and minutes or just minutes.

WARNINGS

Before starting an infusion:
• check that the *reservoir* is correctly connected;
• Inspect the infusion line to ensure there are no folds, *clamps* or other occlusions in the line;
• expel any air bubbles;
• in case different hourly flows are used, check that the time is correctly set.

PRIMING THE INFUSION LINE

The *priming* function allows for filling the infusion line with the drug contained in the reservoir.

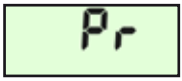
The volume available for *priming* is 1.5 ml.

The *priming* function is enabled when the device is switched on and the pusher is in the infusion start position, regardless of whether the settings lock is on.

The *priming* procedure is as follows:

1. switch on the device as described in the relevant section;

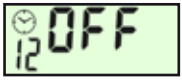
2. the display shows **Pr**. There are three options:



a. postpone the *priming*;
b. cancel the *priming*;
c. perform the *priming*.

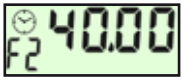
a. Postpone the *priming*

Press the ⊖ and ⊕ buttons together: the pump switches off and the display shows **OFF**. Or wait 10 seconds and the pump switches itself off automatically.



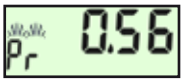
b. Cancel the *priming*

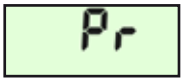
Press the ⊕ button; the pump starts the infusion and the display shows the time remaining until the end of the infusion, as well as the current flow rate.



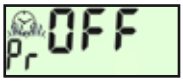
c. Perform the *priming*

Press and hold down the button to deliver the *priming dose;* the *priming* function can be interrupted by releasing the button. The display shows a flashing letter **Pr** followed by the number of millilitres delivered. The display then shows **Pr** again. In this way it is again possible to postpone, cancel or perform the *priming* function. The procedure can be repeated until a maximum of 1.5 ml has been delivered in total.





At the end of this phase, if the infusion is not started by pressing the button, the pump returns to **OFF**.



NOTES

• Every time the pump administers 0.5 ml of drug, it emits an audible signal and pauses for about one second.

• Continue with the priming until the drug arrives at the end of the infusion set. There are no time limits to the *priming* operation.

• If, after the *priming* indication is displayed, the buttons are not pressed again for 10 seconds, the display shows **OFF**.

WARNINGS

• Do not *prime* the infusion set with the tube connected to the patient.

• The *priming* function must only be performed with the *reservoir* attached to the infusion set and before inserting the needle into the infusion site.

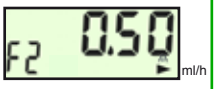
• Before beginning an infusion, check that there are no air bubbles in the infusion line, expelling any that are found. Alternatively, use a vented filter.

• While the displays flashes **Pr** it is not possible to select the programming mode (**FrEE**/**Auto**) or change the partial volume.

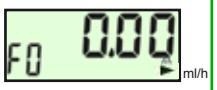
PUMP SWITCHED ON

During the infusion the time indicated on the display is shown in hours (with a flashing letter **h**), or in hours and minutes with the flashing drop icon. If the time "to go" is less than one hour, the time is shown in just minutes, and the flashing "**Minute**" indicator is displayed.

If you press the button, the display temporarily toggles between the "time to go" and the programmed flow rate.



If you have selected the **F0** flow, the display shows **F0** and **0,00**. In this event the drug can only be administered by means of a bolus dose request.



BOLUS DOSE

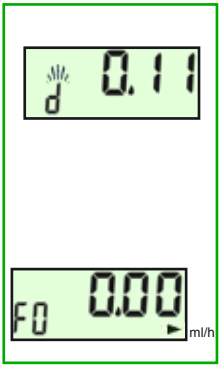
The bolus is a supplementary dose of the drug that the patient can request when it is needed. If the bolus dose volume has been set to 0.00 ml, the bolus dose cannot be administered.

Administration of bolus dose

Bolus doses can only be administered while the pump is in ON condition.

The procedure for their administration is as follows:

1. Press the button; the pump gives a beep and commences to administer the bolus dose, during which a flashing letter **d** is shown on the secondary display**,** while the volume of the bolus dose being administered is shown on the main display. During the bolus dose administration, the pump beeps and pauses for about 1 seconds for every 0.11 ml of drug administered.



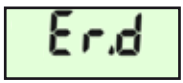
2. At the end of the bolus dose administration, the pump beeps and the display shows the time remaining of the original infusion, or, if the setting is for a flow rate of 0.00 ml/h, it shows **F0,00**.

NOTE

The bolus dose delivery can be interrupted at any time by pressing the ⊕ button.

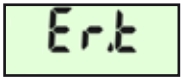
RESTRICTIONS ON THE ADMINISTRATION OF BOLUS DOSES

If the bolus dose volume is set to 0.00 ml, pressing the button will display the **Er,d** error message.



The administration of bolus doses is limited by the **interval between doses** (temporal limitation).
By setting **no,Lt** you can disable this limitation.
Bolus doses cannot be administered during the interval period observed by the function.

During the limitation period, if you request a bolus dose, the display shows **Er,t** (temporal limitation between active bolus doses).

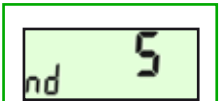


NOTE

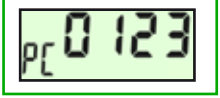
If all the hourly flows are set to **F0**, the display shows **F0,00** with a flashing **F**. Pressing the ⊖ button temporarily displays **F0** with **0.00** ml/h.

DISPLAYING THE NUMBER OF ADMINISTERED BOLUS DOSES DURING AN INFUSION AND THE NUMBER OF INFUSIONS

1 - To check the number of bolus doses administered by the patient during an infusion while the pump is **OFF** or **StoP**, press and hold the ⊖ button for a few seconds and the value will be displayed (**nd** = number of doses).



2 - To check the number of infusions delivered by the device (**PC** = partial counter) while it is **OFF** or **StoP**, press and hold the ⊖ button for about 8 seconds.



WARNINGS

• The number of the administered bolus doses is only available until the beginning of a new infusion; switching the pump on for a new infusion automatically resets the value.

• The number of bolus doses includes those delivered by pressing the button.

WITHDRAWING THE PUSHER

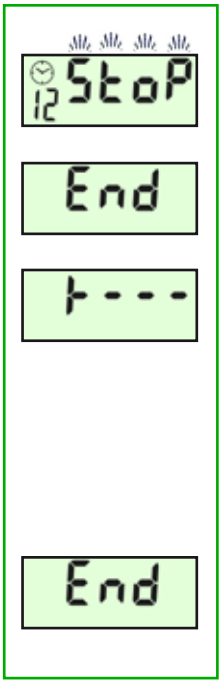
1. Withdrawal of the pusher before the end of the infusion
This function allows the interruption of an active infusion, withdrawing the pusher to the start position of the infusion.

To stop an active infusion, do the following:

• switch the pump off by pressing the button;

• press the and buttons together: the display shows **End** for 10 seconds and then begins to withdraw the pusher;

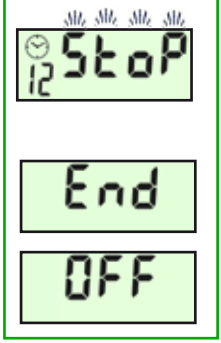
• during the 10 seconds that the display shows **End** you can cancel the withdrawal request by pressing the button.



2. Withdrawal of the pusher at the end of the infusion
Ten minutes before the end of the infusion, the device gives an intermittent beep for 2 seconds. This signal is repeated twice at 5 minutes from the end of the infusion.

At the end of the infusion an intermittent beep is given and the display shows **End**.
After a few seconds, the pusher starts withdrawing until it reaches the start position of the infusion.

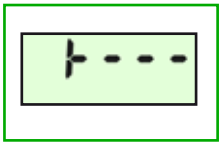
NOTES



• While the display shows **End**, the withdrawal function can be cancelled by pressing the ⊕ button. The display shows **StoP**.

• The withdrawal function can be interrupted by pressing the ⊕ button. The display then alternates between **End** and **OFF**. At this point the only active button is the ⊕ button. When you press again the pump recommences the withdrawal of the pusher.

Pusher in motion
While the pusher is in a continuous withdrawal motion, the display shows the "**pusher continuous withdrawal**" indication.



NOTE

The pusher withdrawal time for a 50 ml volume is approx 6 minutes, and is proportionately less for lower volumes.

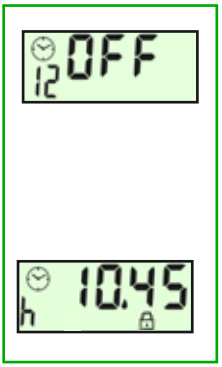
WARNING

Do not remove the *reservoir* until the pusher has been withdrawn to the infusion start position.

SWITCHING OFF THE PUMP

To switch off the device, press the ⊕ button. The display will show **StoP**. If the pump is switched off during an infusion, the device will emit a series of 10 short beeps every 10 seconds, and the display will flash the **StoP** message. To suppress the audible signals, press the ⊖ button.

DISPLAYING THE SETTINGS



This function displays the programmed pump settings.
To display the pump settings, the pump must be set to **OFF** or **StoP**.

If the settings are displayed when the settings lock is set to **L0** (settings lock off) the settings flash, and can be modified.
If the setting are displayed when the settings lock is set to **L1** (settings lock on, with the display showing the "lock" indicator), the parameters do not flash and are not modifiable (with the exception of the time - see page 61).

Proceed as follows:

1. press the button for about 4 seconds: the display shows the time;

2. do not press any button for about 20 seconds, and the display will go back to **OFF** or **StoP**;

3. press the button again to show the other settings in sequence: **hours**, **minutes**, **bolus dose volume**, **interval between bolus doses**, **flow rates**, **flows over the daily 24-hour period** and **partial volume**.

NOTES

- When the settings lock is on (**L1**), you can, if needed, change the time settings using the following procedure:

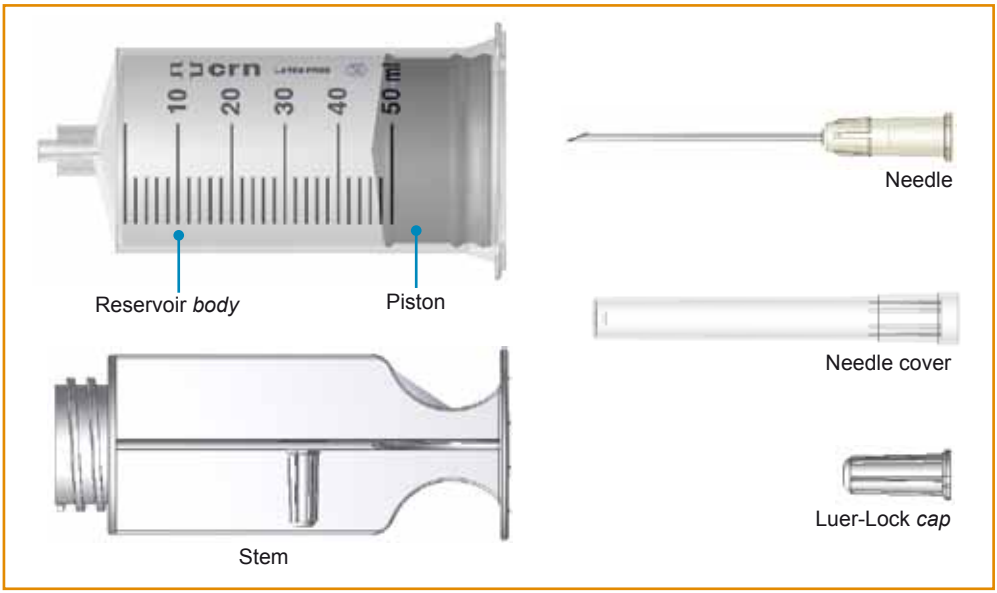
1. press the button for about 1 second: the display shows the flashing hour and minute settings;
2. press the button. The hour value begins to flash and you can change the hour and minute settings. This function can be used, for example, if you transfer to a different time zone.

- To display the flows assigned over the daily 24-hour period, press the button.

RESERVOIR *PARTS*

The ***CRONO*** **PAR 50** pump uses dedicated 50 ml *reservoirs*, model CRN® CRONO® Syringe.

The *reservoirs* are: single-use, non-pyrogenic to be used only if the packaging is undamaged.



WARNING

For safety reasons, you are recommended to use the original CRN® *reservoirs* Crono® *Réservoir*.

The use of any other type of *reservoir* could damage the pump and harm the patient.

CANÈ S.p.A. disclaims all responsibility if the device is used with a non-original *reservoir* different from that recommended.

LUER-LOCK *CAP FUNCTIONS*

- After the *reservoir* has been filled, the cap facilitates the unscrewing of the stem, avoiding spillage of the pharmaceutical;

- it facilitates the correct connection between the pump pusher and the rubber piston of the *reservoir;*

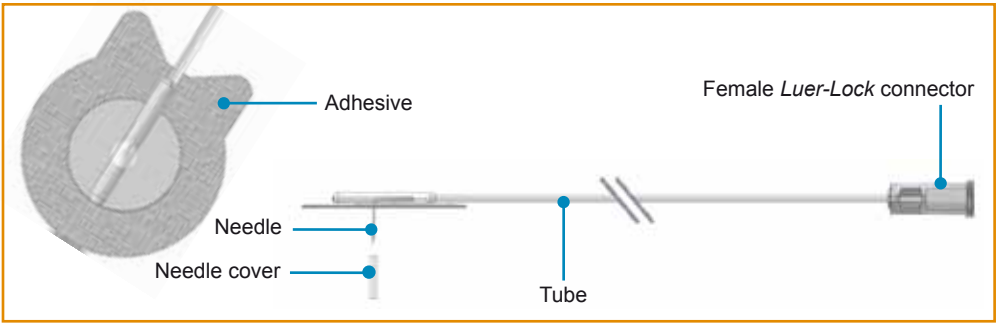
- it protects the drugs inside the *reservoir* in case it is not used immediately.

INFUSION SET

You are recommended to use an infusion set with the following characteristics:

- internal volume of reduced tube (ideal 0.1 ml, maximum 0.62 ml);
- tube length not more than 90 cm;
- anti-kink tubing.

INFUSION SET PARTS



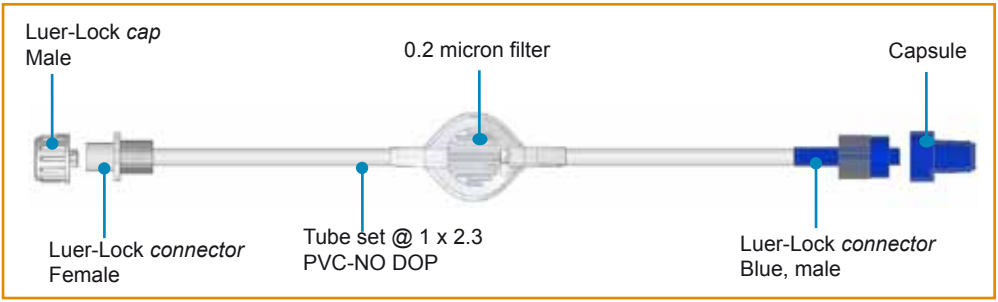
NOTE

The images show the Neria™, infusion set from Unomedical, a Convatec Company.

FILTRAJET

For a safe infusion you are recommended to use a filter in order to:

- prevent bacterial infections;
- eliminate air from the *reservoir* and the infusion set;
- capture micro-particles such as those from glass or plastic.



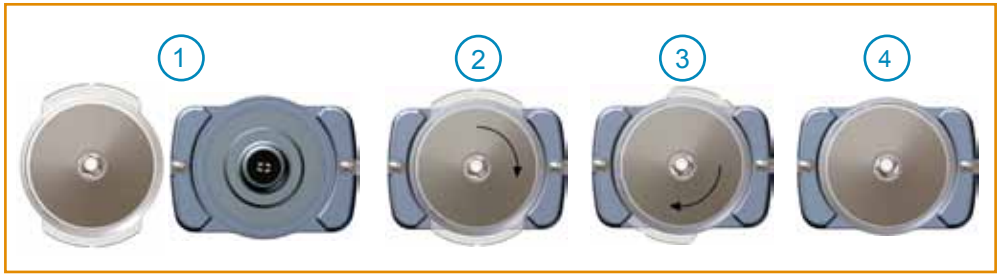
PREPARING THE *RESERVOIR* AND CONNECTING TO THE PUMP

1. Screw the needle into the *reservoir* in a clockwise direction and remove the needle cover;
2. fill the *reservoir*, aspirating the liquid slowly and checking that the quantity of the drug does not exceed its capacity or any partial volume you may have set;
3. screw the *Luer-Lock* cap to the *reservoir* (a) and then unscrew the stem, rotating it counter-clockwise (b) with a fairly rapid movement;
4. connect the *reservoir* to the pump; the rubber piston will be inserted into the pusher. Rotate it clockwise through 90° and it will click and engage with the pusher;
5. insert the cone of the infusion set over the *reservoir*.

CONNECTION OF THE *RESERVOIR* TO THE PUMP

Insert the dedicated CRN *reservoir* into the pump and engage it by rotating it 90° clockwise; a click confirms it has engaged.

Front view of the pump



WARNING

1 - Before filling the *reservoir*
Unscrew and screw back the piston rod to facilitate its unscrewing after you have filled the *reservoir*.

2 - Filling the *reservoir*
The liquid must be aspirated slowly.
Do not fill the *reservoir* more than the maximum level allowed of 50 ml.
The rod must be unscrewed with a fairly rapid movement.

3 - Connection of the *reservoir* to the pump
To avoid any leakage of the drug while the *reservoir* is being connected to the pump, you can use the infusion set, as an alternative to the *Luer- Lock* cap indicated on page 78.

While connecting the *reservoir* to the pump, hold them as shown in the figure.

When making the connection, avoid exerting any pressure on the *reservoir* walls, because this could cause liquid to leak past the piston rings.

While filling the *reservoir* and connecting it to the pump, a small leakage might occur between the first and second rings on the rubber piston. This does not compromise either the correct working of the *reservoir* or the delivery of the drug.

INFUSION SITES

The images below show the recommended infusion sites.
You are recommended to change the injection site after every infusion to avoid skin irritations.

FRONT

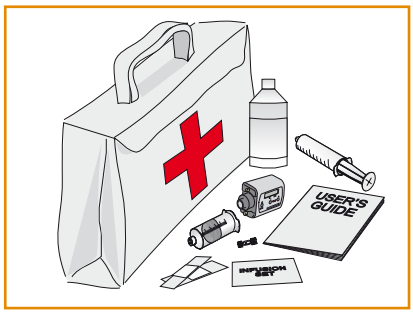
BACK

PREPARING FOR THE INFUSION

Before preparing for the infusion, you are recommended to adopt the following precautions:

1. wash your hands;

2. prepare a clean working environment.



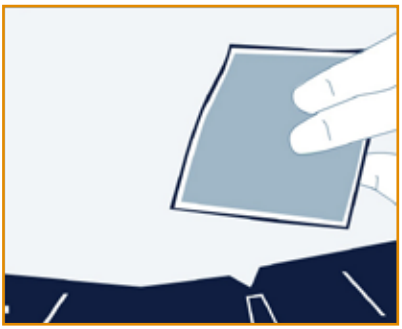
WARNINGS

- Always work in antiseptic conditions, to reduce the risk of infection to the minimum.

- Warning, apomorphine stains clothing and objects.

The images refer to the Neria™ infusion set from Unomedical, a Convatec Company.

Disinfect the infusion site following the instructions of the relevant medical personnel. Ensure that the area of the infusion site is dry before inserting the subcutaneous needle.



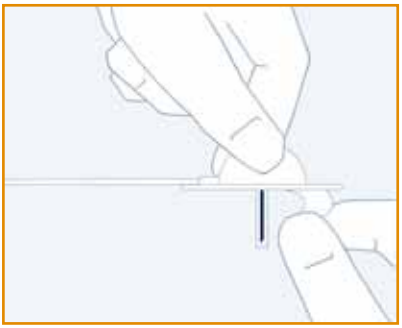
Connect the infusion set to the *reservoir*.

Hold the infusion set by the wings. Prime the infusion line manually or use the *priming* function of the pump (**Auto**). Ensure there are no air bubbles in the infusion line.

WARNING

When you are priming the infusion line and are preparing to insert the needle below the skin, hold the set with the needle pointing downwards to ensure that none of the drugs can come into contact with the protecting adhesive paper.

Remove the protective adhesive paper.

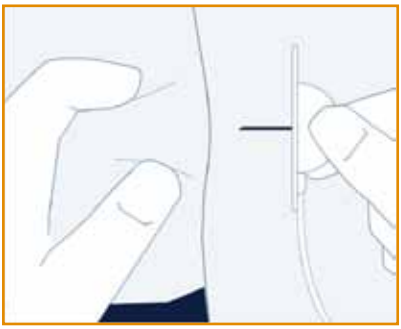


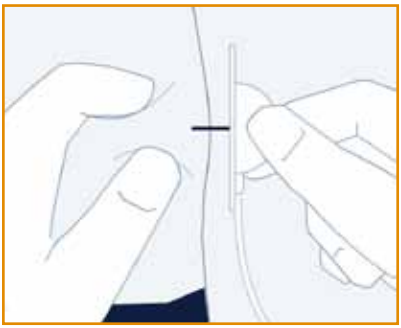
Remove the needle cover, extracting it with care, before inserting the needle.

WARNING

Be careful not to touch the Neria™ needle when you remove the protection.

It is important to lift a fold of skin, to reduce the risk of positioning the needle in a muscle. Pinch the skin with your fingers at the chosen infusion site before inserting the needle, which you do by taking the protective wings of the infusion set with the other hand and inserting the needle vertically.





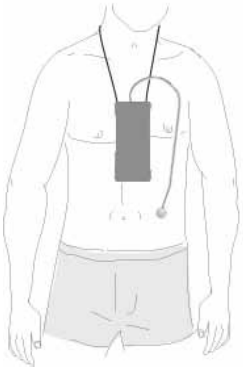
Press firmly on the adhesive to fix it to the skin. Check the infusion site frequently to ensure that the needle remains in the correct position.

HOW TO USE THE SUPPLIED STANDARD EQUIPMENT

The following figures give an indication of how to use the standard accessories supplied with the pump.

PUMP CARRIED AROUND THE NECK

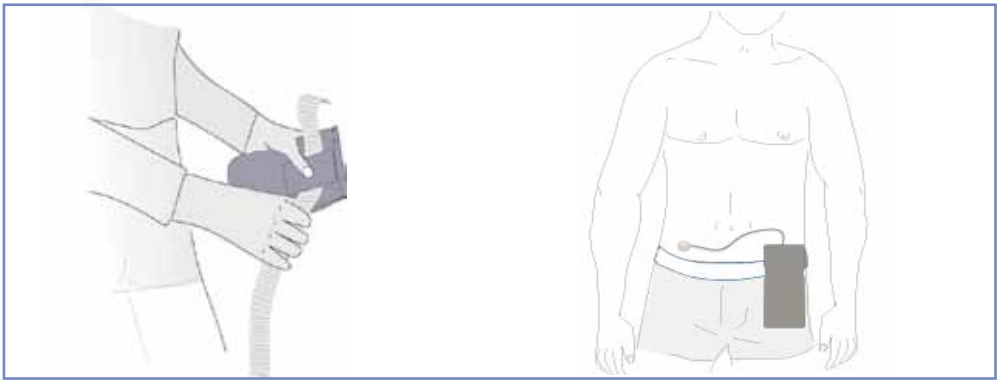
The pump worn with a collar strap and a fabric case.



FASTENING THE PUMP COLLAR STRAP

WEARING THE PUMP AT THE WAIST

The pump worn with an elastic belt and a fabric case.



GENERAL WARNINGS

The device can be damaged by liquid, so it must not be kept on while in the bath or the shower, etc. If the device is accidentally made wet, (for example, with drops of the drug, or by bedwetting), you must ensure it is checked by the CANÈ S.p.A. Service Centre.

The device must be kept away from:
- sources of heat (radiators, gas rings, stoves);
- the direct rays of the sun;
- strong electromagnetic fields (magnets, loudspeakers, mobile devices), details are supplied in APPENDIX 6;
- ionizing radiation;
- ultrasound devices;
- MRI devices.

The device does not need sterilising.

Do not freeze the CRN *reservoir* with the drug still in it.

The device must not be placed in a fridge or freezer.

The device must not be placed in an oven or microwave.

Reservoirs, infusion sets, needles, filters and all consumables must be disposed of in an appropriate way, using containers designed for this purpose.

If you do not observe the above warnings, the device could malfunction, with potentially serious consequences for the user.

MANUAL UPDATES

The version and the date of publication of this User Guide are given on every page. When a year has passed between the publication date (given on page 3) and the use of the product, the doctor should contact CANÈ S.p.A. to determine if a more recent version of the manual has been published.

MAINTENANCE

The technical characteristics of the device make it extremely simple to maintain.

If the device is damaged, you are recommended to have it checked by the CANÈ S.p.A. Customer Support Service before re-using it.

The external surfaces can be cleaned with a lightly dampened soft cloth, using a mild detergent or disinfectant.

GENERAL WARNINGS

- Do not immerse the pump in detergent solutions or water.
- Avoid getting liquids inside the pump. If the device gets wet, immediately try to dry it with absorbent paper.
- Do not clean the pump with acetone, solvents or abrasive detergents.
- Do not sterilise the pump.

STORAGE

If the device is not used for a period of more than one or two months, you are recommended to remove the battery and put the pump away in its case in a dry place at room temperature.

DISPOSAL

At the end of the expected life of the pump, contact CANÈ S.p.A. Customer Support Service which will provide you with necessary instructions about the disposal of the device.

Reservoirs, infusion sets, needles, filters and all consumables must be disposed of in an appropriate way, using containers designed for this purpose.

EXPECTED PUMP LIFE

The pump is expected to last for 4 (four) years from its purchase date. For safety reasons you should not continue to use it after this period.

SUPPORT

The device must only be repaired by CANÈ S.p.A. Customer Support Service. You are recommended, before sending the device, to contact:

- **Servizio Assistenza Clienti (Customer Support Service)**
  CANÈ S.p.A. Medical Technology
  Via Cuorgnè, 42/a
  10098 Rivoli (Turin) - Italy
  Tel. +39.011.9574872
  Fax +39.011.9598880

- **CANÈ S.p.A. Online**
  Internet: www.canespa.it - E-mail: service@canespa.it

  Service available Monday to Friday from 8.30 to 17.00.

GUARANTEE

CANÈ S.p.A. guarantees that the product is free from any material or manufacturing defects for a period of 2 (TWO) YEARS from the original date of purchase.

If, in the course of this guarantee period, any material or manufacturing defects are identified, CANÈ S.p.A. will repair or substitute the defective components according to the terms and conditions herein, without any charge for labour or parts; the client is responsible for the costs of sending the pump to the CANÈ S.p.A. Customer Support Service.

CANÈ S.p.A. reserves the right to change the characteristics or model of its devices, without being under any obligation to make corresponding modifications to devices already manufactured and sold.

Conditions:

1. The guarantee is valid only if the defect is reported within the period of the guarantee.

2. This guarantee does not extend to any costs and/or defects following modifications or adaptations made to the product, without prior written authorisation by CANÈ S.p.A.
CANÈ S.p.A. disclaims all responsibility either to the purchaser or to third parties for damage that occurs to persons or things as a result of improper operation of the device, for uses of the device for which it was not designed and for the non-observance of the instructions provided in the User Guide. The purchaser undertakes to indemnify CANÈ S.p.A. from any claims by third parties with respect to the above.

3. This guarantee is not valid if the model or serial number of the product have been modified, erased, removed or have in any way been made illegible.

4. The following are excluded from the guarantee:
• periodic maintenance
• damage consequent to improper use, including but not limited to:
- incorrect power supply;
- use of the product for purposes other than those for which it is designed;
- repairs performed by unauthorised personnel or by the Customer;
• accidental and unintentional events, such as liquid spills and falls;
• natural events and malicious or negligent acts;
• the standard equipment supplied with the pump.

5. CANÈ S.p.A. undertakes to perform repairs on the device for a period of not more than 4 (four) years from the date of purchase.

After that period, CANÈ S.p.A. has no further obligations to make repairs. CANÈ S.p.A. disclaims all responsibility either to the purchaser or to third parties for damage that occurs to persons or things as a result of the use of the device after 4 (four) years from the date of purchase.

6. After the guarantee period is expired, support will be provided by CANÈ S.p.A. with the customer bearing the subsequent costs of replaced parts, labour and transport in effect at the time.

7. The company disclaims any liability with respect to the patient and/or third parties for any health problems and/or inconvenience resulting from the period when the device is being repaired.

8. The company disclaims any liability with respect to the patient and/or third parties for any problems and/or delays associated with the shipping of the device.

DECLARATION OF CONFORMITY

CE

0476

The company CANÈ S.p.A., with headquarters in Via Cuorgnè, 42/a 10098 Rivoli (Turin) - Italy, manufacturer of the medical device ***CRONO*** **PAR 50** ambulatory infusion pump with *reservoir* for drug administration,

Serial no.

declares that the device conforms to the essential requirements of Appendix I of Directive 93/42/CE, modified by Directive 2007/47/CE, as per certificate MED 9813 provided by the Notifying Body no. 0476 according to Appendix II of the same Directive, and is released to the market in compliance with the corresponding laws of the individual European member states.

Rivoli, 12/07/2012

The Chairman

APPENDICES

ICONS USED ON THE PUMP

SN	**Serial no. of the pump**
IP 42	**IP protection rating** 1st digit (4) = protection from solid objects larger than 1 mm. 2nd digit (2) = protection from water droplets sprayed at an angle up to 15º degrees.
CE 0476	**CE marking**
	**Electro-medical device** Type BF
	**Warning: read instructions before use**
	**Sorted waste collection for electrical and electronic devices** **In accordance with article 13 of Legislative Decree no. 151 of 25 July 2005 "Implementation of Directives 2002/95/EC, 2002/96/EC and 2003/108/EC concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment, as well as the disposal of waste."** The symbol of the crossed out waste bin on the product and its packaging indicates that at the end of its useful life, the product must be disposed of separately from other waste. Sorted waste disposal of products at the end of their life is organised and managed by the manufacturer. Users wishing to dispose of this device must therefore contact the manufacturer (or the appropriate local distributor) and use the system which has been devised to allow for the separate disposal of devices at the end of their life. A proper differentiated collection system for devices destined for recycling, treatment and environmentally compatible disposal helps reduce the potentially negative impacts on the environment and health, and facilitates the re-use or recycling of the materials from which the device is constructed. The illegal disposal of a product is punishable according to the laws currently in force. **Note**: The symbol displayed on the product label is, for obvious reasons of space, reduced and simplified with respect to the specifications in the reference standard CENELEC EN50419.

ICONS USED ON THE *RESERVOIR* BLISTER PACK

	**Read the instructions**
CE 0123	**CE marking**
	**Recyclable**
	**Use only once**
	**Non-pyrogenic**
	**Keep dry**
	**Keep away from sunlight**
	**Expiry date**
STERILE EO	**Sterilised with ethylene oxide**
PP	**Polypropylene**
LOT	**Batch code**
REF	**Reference no.**
NEEDLE	**Needle size**

OPTIONAL ACCESSORIES AVAILABLE ON REQUEST

1. Vertical leatherette case, similar to a mobile phone case.

Detail of opening system with aperture for infusion set

Detail of belt clip

Colours: 

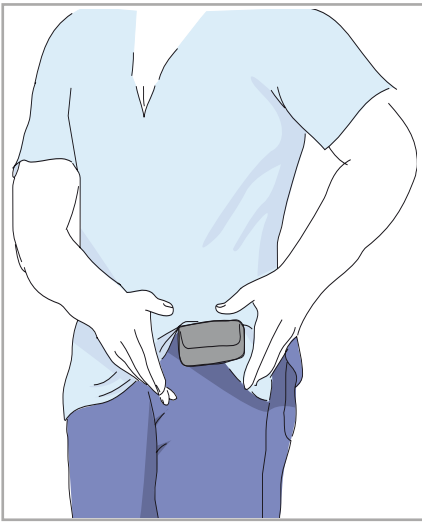
Dimensions: 16 x 5.5 x 4 cm

Weight: about 60 g

Item code: CM/17/A

2. Horizontal leatherette case, similar to a spectacle case.

Detail of belt clip



Colours: 

Dimensions: 16 x 5.5 x 4 cm

Weight: about 50 g

Item code: CM/22/A

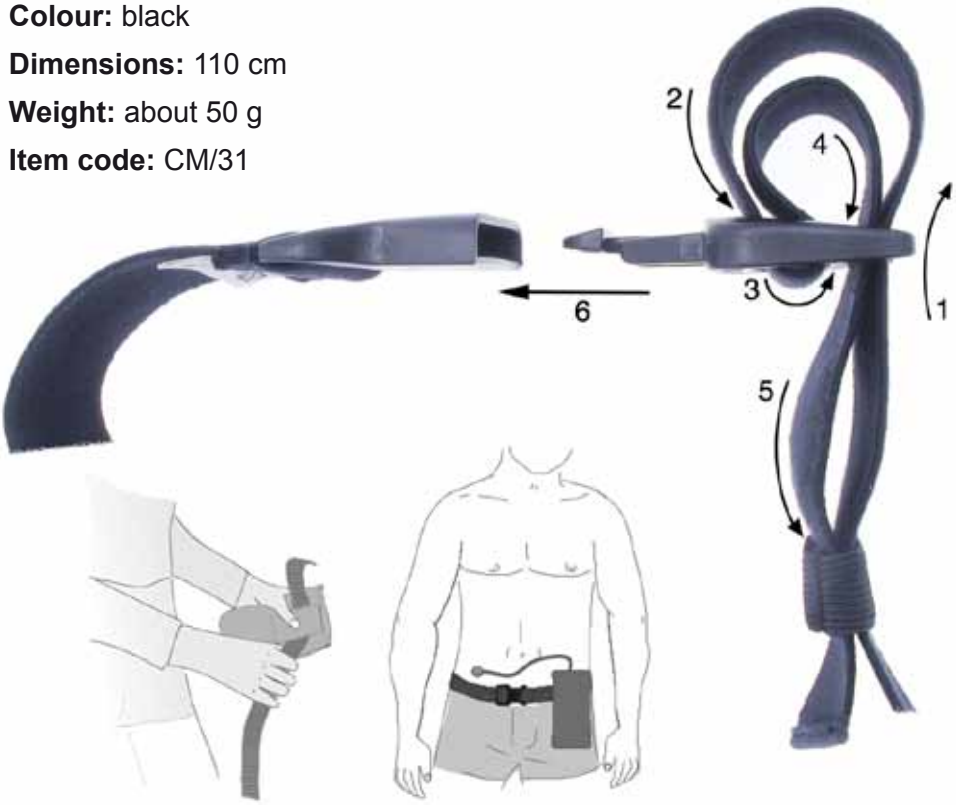
3. Adjustable elastic belt with buckle.

Colour: black

Dimensions: 110 cm

Weight: about 50 g

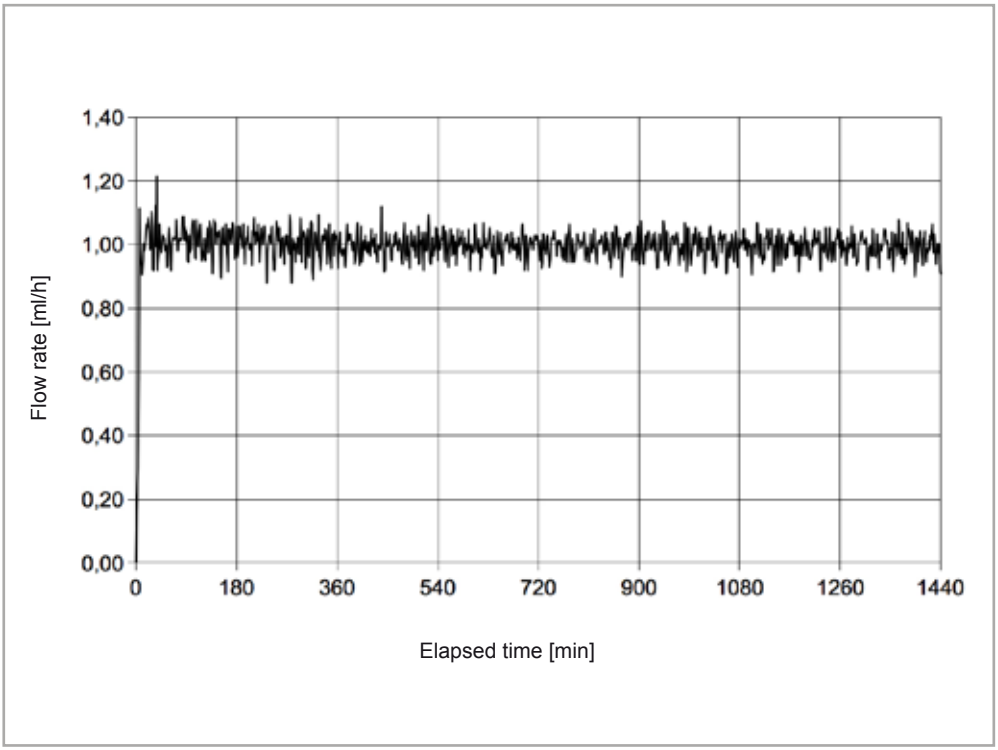
Item code: CM/31



PRECISION TEST (TRUMPET CURVE)

The tests have been performed according to IEC 60601-2-24, Electro-medical devices, Part 2: Particular requirements for the safety of infusion pumps and controllers. The following graphs show the precision of the pump during the administration of the drug.

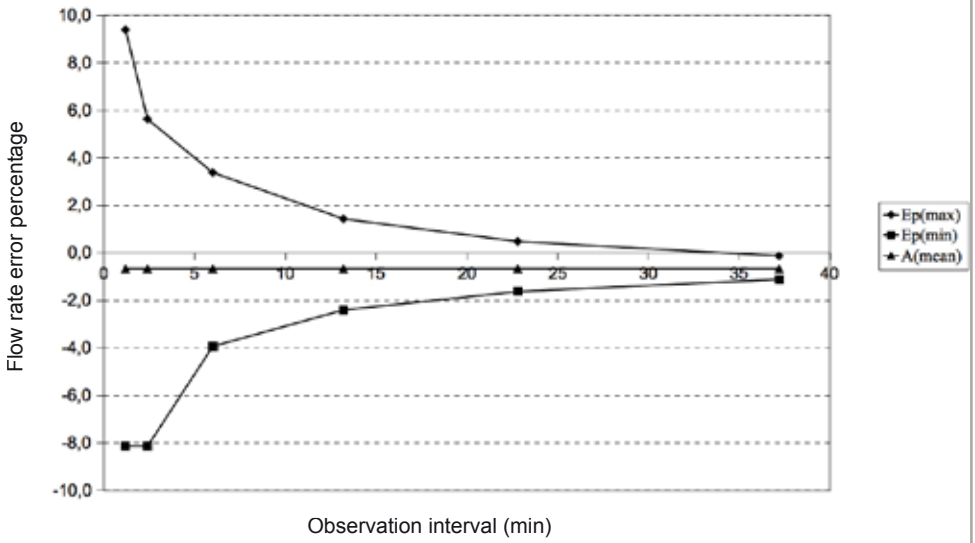
1.1 – Start-up flow
• Flow rate setting: 1 ml/h.



TRUMPET CURVE

1.2 - Flow rate error (trumpet curve)

• Flow rate setting: 1 ml/h.



The actual degree of precision may differ from that indicated in this manual, depending on the type of accessories and extension tubes used in the administration line of the drug.

Legend:

E_p(max.) = maximal percentage variations.

E_p(min.) = minimal percentage variations.

A(mean.) = mean percentage variations.

PRESSURE LEVELS (PL)

The ***CRONO*** **PAR 50** pump allows the medical/paramedical and clinical engineering personnel, as well as the distributor, to set the occlusion pressure level (**PL**).

The device is provided with the occlusion pressure level set to **PL2** (2.2 bar +/-1).

This level may be insufficient for the demands of the patient and/or for the technical specifications of the infusion line (e.g. the device signals constant occlusion conditions), or it may be too high (infusion line not designed for the set pressure value). In this case the pressure can be decreased by setting **PL1** (1.8 bar +/- 0,8) or increased by setting **PL3** (3.2 bar +/-1,2).

NOTE

Pressure level summary table.

LEVEL	PRESSURE
PL1	1.8 bar +/- 0.8.
PL2	2.2 bar +/- 1
PL3	3.2 bar +/- 1.2.

WARNINGS

• Information on the selection of the pressure level (**PL**) is available in **APPENDIX 10** "**ACCESSING RESERVED SECTION**", and must not be provided to the patient.

• Changing the occlusion pressure will vary the time needed to signal an occlusion and the post-occlusion bolus volume, as indicated in the enclosed tables.

TIME NEEDED TO SIGNAL AN OCCLUSION

The time needed to signal an occlusion is the interval between the beginning of the occlusion condition and the recognition of the condition by the pump. This value depends on the flow rate, because the lower the flow rate, the longer will be the time needed by the pump to recognise the occlusion condition. The values given here consider the time needed jointly by the pump and the *reservoir* to signal the occlusion.

PL1	
Flow rate	**Time needed to signal an occlusion**
0.2 ml/h	About 5 h 15 min
1 ml/h	About 50 minutes
5 ml/h	About 10 minutes

PL2	
Flow rate	**Time needed to signal an occlusion**
0.2 ml/h	About 6 h 50 min
1 ml/h	About 1 h 15 min
5 ml/h	About 15 minutes

PL3	
Flow rate	**Time needed to signal an occlusion**
0.2 ml/h	About 7 h 45 min
1 ml/h	About 1 h 30 min
5 ml/h	About 20 minutes

WARNINGS

• The time needed to signal an occlusion is dependant on the flow rate, because the lower the flow rate, the longer will be the time needed by the pump to activate the occlusion alarm.
• The time needed to signal the occlusion can increase if there is air in the line, if you are using catheters, filters and extension tubes of other dimensions, or in an elastic material, or when the line from the pump is connected to other devices.
• For patients who could suffer severe harm if there is an interruption in the administration of the drug by the pump, arrangements must be made for them to be under the strict supervision of a doctor who can take any immediate corrective action required.

POST-OCCLUSION BOLUS

When the occlusion alarm sounds, the pump has detected an excessive back pressure in the infusion line. This back pressure must be removed in order to avoid releasing a post-occlusion bolus, which might cause serious harm to the patient. The volume of a ***CRONO*** **PAR 50** post-occlusion bolus, considering only the combined volume of the pump and the *reservoir*, is:

- about 1.0 ml (**PL1**);
- about 1.2 ml (**PL2**);
- about 1.5 ml (**PL3**).

WARNINGS

- The volume of the bolus dose released post occlusion can increase if there is air in the line, if you are using catheters, filters and extension tubes of other dimensions or of a softer material, or when the line from the pump is connected to other devices.

- After the occlusion alarm sounds, take any and all measures appropriate to avoid the administration of a post-occlusion bolus to the patient.

- Patients who might suffer severe harm from the accidental release of a post-occlusion bolus must receive adequate instructions and/or training from medical or paramedical personnel on how to proceed in such a situation.

ELECTRO-MAGNETIC COMPATIBILITY

The electro-magnetic compatibility tests were performed in compliance with the standards:

• IEC 60601-2-24:2012, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers;

• IEC EN 60601-1-2 Ed. 2, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility – Requirements and tests.

Guide and declaration by the manufacturer - electro-magnetic emissions		
***CRONO* PAR 50** is designed to operate in the electromagnetic environment specified below. The client or user of the ***CRONO* PAR 50** must ensure that it is operated in such an environment.		
Emission test	**Compliance**	**Electro-magnetic environment - guide**
CISPR 11 RF emissions	Group 1	***CRONO* PAR 50** uses RF energy only for its internal operation. As a consequence, its RF emissions are very low and would thus not be expected to cause any interference to electronic devices in the vicinity.
Emissions in RF CISPR 11	Class B	***CRONO* PAR 50** is designed for use in all environments, including domestic environments and those environments directly linked to the low voltage mains supplying residential buildings.
Harmonic emissions IEC 61000-3-2	N/A	
IEC 61000-3-3 emissions in the event of voltage fluctuations or flicker	N/A	

Guide and declaration by the manufacturer - electro-magnetic immunity			
***CRONO* PAR 50** is designed to operate in the electromagnetic environment specified below. The client or user of the ***CRONO* PAR 50** must ensure that it is operated in such an environment.			
Immunity test	**IEC 60601 test level**	**Level of compliance**	**Electromagnetic environment - guide**
IEC 61000-4-2 electro-static discharge (ESD)	15 kV in air, 8 kV on contact	15 kV in air, 8 kV on contact	The flooring must be wood, concrete or ceramic. If the floor is covered in a synthetic material, the relative humidity must be at least 30%.
Electro-magnetic fields	400 A/m 50 and 60 Hz	400 A/m 50 and 60 Hz	

Guide and declaration by the manufacturer - electro-magnetic immunity			
***CRONO* PAR 50** is designed to operate in the electromagnetic environment specified below. The client or user of the ***CRONO* PAR 50** must ensure that it is operated in such an environment.			
Immunity test	**IEC 60601 test level**	**Level of compliance**	**Electromagnetic environment - guide**
Radiated immunity	80-2500 MHz 10V/m AM 80% 1 KHz	10V/m	Interference could occur in the vicinity of devices marked with the following symbol: 
	20-80 MHz 10V/m AM 80% 1 KHz	10V/m	

Recommended separation distance between mobile and portable radio communication devices and the *CRONO* PAR 50		
***CRONO* PAR 50** is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The client or user of the ***CRONO* PAR 50** can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable communication devices using RF (transmitters) and the ***CRONO* PAR 50** as recommended below, relative to the maximum output power of the radio-communication devices.		
Maximum specified output power of transmitter (W)	**Separation distance at the transmitter frequency (m)**	
	150 kHz to 80 MHz	**80 MHz to 800 MHz**
0.01	1.2	0.12
0.1	3.8	0.38
1	12	1.2
10	38	3.8
100	120	12

REFERENCE DIRECTIVES

- **Council Directive 93/42/EEC:** Medical devices.

- **Legislative Decree no. 46, 24th February 1997.** Implementation of Council Directive 93/42/EEC concerning medical devices.

- **Directive 2007/47/EC of the European Parliament and of the Council:** Amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

- **Legislative Decree No. 37, 25 January 2010**. Implementation of Directive 2007/47/EC.

TECHNICAL STANDARDS

• **IEC EN 60601-1:2007-05.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance.

• **IEC EN 60601-1/EC:2010-05.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance.

• **IEC EN 60601-1-1:2003-06.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Safety requirements for electromedical systems.

• **IEC EN 60601-1-2/A1:2006-10.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility – Requirements and tests.

• **IEC EN 60601-1-2:2010-01.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility – Requirements and tests.

• **IEC EN 60601-1-4:1997-08.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – 4. Collateral standard: Programmable electromedical systems.

• **IEC EN 60601-1-4/A1: 2000-06.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Programmable electromedical systems.

• **IEC EN 60601-1-8:2009-11.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Alarm systems - General requirements, tests and guidance for alarm systems in medical electrical equipment and electromedical systems.

• **IEC EN 60601-1-11:2011-07.** Medical electrical equipment, Part 1: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

• **IEC EN 60601-2-24:2012-10.** Medical electrical equipment, Part 2: particular requirements for the safety of infusion pumps and controllers.

• **IEC EN 60529: 1997-06.** Degrees of protection provided by enclosures (IP Code).

• **IEC 62-108: 2000-05.** User Guide to the maintenance of infusion pumps and control systems.

• **IEC EN 62353:2008-11.** Medical electrical equipment - recurrent checks and tests after repair of medical electrical equipment.

• **IEC 62-122: 2002-07.** User Guide to acceptance testing and periodic maintenance of the safety and/or performance of medical devices powered by a specific power source.

• **IEC 62-143: 2007-05.** Table of correspondence between articles (clauses) in publication IEC 60601-1:2006 and those of its 1988 edition, and its subsequent modifications.

• **IEC EN 62304:2006-10.** Medical device software – Software life cycle processes.

SETTINGS

CANÈ MEDICAL TECHNOLOGY	CRONO PAR 50 THERAPEUTIC SETTINGS	Mod. SV 02/01 Date: 10.04.13

CRONO PAR 50 S.N.		Patient	.....
Version set	❑ FrEE ❑ Auto		.....

VERSION FrEE

BOLUS DOSE d (0,00 - 2,00 ml)	..... ml	F1 (0,05 - 5,00 ml/h)	..... ml/h
INTERVAL TIME BETWEEN TWO BOLUSES it (no limit - 24 h)	❑ ..... h ..... min ❑ no,Lt	F2 (oFF - 0,00 - 5,00 ml/h)	..... ml/h
		F3 (oFF - 0,00 - 5,00 ml/h)	..... ml/h
VOLUME cc (1 - 50 ml)	..... ml	KEYBOARD LOCK LEVEL	❑ L 0 (Unlocked) ❑ L 1 (Locked)

VERSION Auto

BOLUS DOSE d (0,00 - 2,00 ml)	..... ml	F0	ZERO FLOW
INTERVAL TIME BETWEEN TWO BOLUSES it (no limit - 24 h)	❑ ..... h ..... min ❑ no,Lt	F1 (0,05 - 5,00 ml/h)	..... ml/h
		F2 (0,05 - 5,00 ml/h)	..... ml/h
		F3 (0,05 - 5,00 ml/h)	..... ml/h
VOLUME cc (1 - 50 ml)	..... ml	KEYBOARD LOCK LEVEL	❑ L 0 (Unlocked) ❑ L 1 (Locked)

Time / Flow	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
F0																								
F1																								
F2																								
F3																								

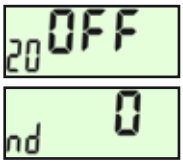
CANÈ S.p.A. Medical Technology - Via Cuorgnè 42/a - Rivoli (TO) Tel. 011.9574872 - Fax 011.9598880
Internet www.canespa.it E-mail: mailbox@canespa.it

ACCESSING RESERVED SECTION

You can access additional reserved functions of the pump, such as: resetting the number of partial infusions, displaying the number of total infusions, displaying the firmware version of the pump, setting the occlusion pressure threshold, setting the date and time.

Procedure:

1 - with the device **OFF**, press the button for about 7 seconds, until the display shows first the **number of bolus doses administered** (**nd**) during the last infusion, followed by the **number of partial infusions** (**PC**) delivered;

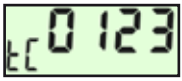


2 - press the button (without releasing the button), and the number of infusions starts to flash. Release both buttons and press the button again. In this phase the arrow indicating **PROG** is displayed and you can choose one of the following:

a) reset the partial infusion counter to zero by pressing the or button, or,

b) continue programming or displaying by pressing the button, as follows.

3 - Press the button again and the display will show the **total number of infusions**.



4 - Press the button again and the display will show **the firmware version (release)**.

5 - Press the button again to display the flashing **occlusion pressure level**: you can select one of the three available levels (**PL1**, **PL2**, **PL3)** by pressing buttons or .

6 - By pressing the button once more, it is possible to set the current time by changing the two flashing digits on the left of the drop icon.

By subsequently pressing the button it is possible to set the two flashing digits on the right of the drop icon, that represent **the minutes.**

You can select the desired hours and minutes values by pressing the buttons or .

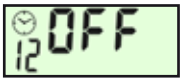
7 - By pressing the button once more, it is possible to set the date by changing the two flashing digits displayed on the left, which represent **the day.**

By subsequently pressing the button it is possible to set the two flashing digits on the right, that represent **the month.**

By subsequently pressing the button it is possible to set the four flashing digits that represent **the year.**

You can select the desired day, month and year by pressing the buttons or .

8 - If you do not press any button for 20 seconds, the selected year (or any other previous parameter) will become steady, the pump exits the reserved functions mode and the display shows **OFF/StoP.**



NOTE

If you keep pressing either the or the button, it is possible to quickly change the hours and minutes.

INFORMATION

For further information on the ***CRONO*** **PAR 50** pump, contact:

Servizio Assistenza Clienti (Customer Support Service)
CANÈ S.p.A. Medical Technology
Via Cuorgnè, 42/a
10098 Rivoli (Turin) - Italy
Tel. +39.011.9574872
Fax +39.011.9598880
Internet: www.canespa.it E-mail: service@canespa.it

Service available Monday to Friday from 8.30 to 17.00.

NOTES